a CDMU publication

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Part I.
A Graded List of
Essential Drugs for India

Part II.
Selected Monographs

A Sequel of
The International Seminar on Rational Use of Drugs
held in April 22-24, 1995 at Siliguri, India

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This manual is published by the CDMU in the interest of the common people in India, majority of whom do not have access to essential drugs.

The opinions expressed in the manual are those of the authors and the CDMU feels proud to subscribe to most of those views.

The readers are requested to write to the Editor their response and comments on the contents of this manual.

Acknowledgement :

The publication of this manual could not have been made possible without the spontaneous and active support and co-operation received from :

- **Rational Drug Compaign Committee, West Bengal.**
- **Consumers' International (Formerly IOCU), Malaysia.**
- **Voluntary Health Association of India, New Delhi.**
- **Paschimbanga Vigyan Mancha.**
- **Government of West Bengal.**
- **Indian Medical Association.**

Foreword

This effort of CDMU to prepare a concensus list of Essential Drugs for India, in keeping with the WHO guidelines oriented it's consultation in the perspective of the socio-economic and morbidity situations prevailing in India. The experts also considered different factors related to the health economics of this country in general and the health care needs of the majority of the population in particular. The Essential Drugs List (EDL), may also be considered as an important tool for propagating the concept of and for involving all sections engaged in the movement for the rational use of drugs. The experts urged upon the Government to ensure availability of the drugs of this list at affordable cost to all the people who need them. The Government should also encourage the indigenous industry to produce these essential drugs. The quality of the drugs must also be assured through a close monitoring network.

Health is a fundamental right of the people. Drugs alone cannot solve health problems, yet definitely can help restoring it by keeping the diseases away through their rational use. The concept of an EDL was originally created by India in the year 1975 by an expert committee under the chairmanship of Sri Jai Sukhlal Hathi, in the oft-refered-to 'Hathi Committee Report' even before the initial model list of essential drugs was included in the first report of the WHO Expert Committee in the year 1977. Two decades have already passed, unfortunately the recommendations of the Hathi Committee Report were largely ignored in India, whereas many developing countries have already formulated their National Drug Policies in consonance with these recommendations. The official India Government representative to the International Conference in Alma Ata in 1978 promised that the Government of India would transform the lives of the vast sections of ailing poor children, women and men of the country by giving a new direction to the health care services, formulating and implementing a national health policy with Primary Health Care as the key element. However, the steps taken subsequently by the Government are in clear contradiction to the promise made. Essential drugs at affordable price is one of the prime component of the Primary Health Care concept. There has been no attempt to even prepare an EDL for the country, by the government. The New Drug Policy announced by the government in 1986 and the recent (1994) modification of Drug Policy - 1986 under the liberalisation policy of the government are much against the spirit of the Hathi Committee Report and would surely go a long way to further jeopardise the health care delivery system and the poor people of our country will be denied of their right to essential drugs.

In this backdrop, CDMU's effort in organizing the International Seminar on Rational Use of Drugs in April 22-24, 1995 at Siliguri, India, in order to formulate an EDL for our country by the of national and international experts was an extremely essential exercise. This effort would prove worthwhile only if all the sectors engaged in health care delivery in India agree to accept it as a guideline to formulate their respective formularies.

M. Sarkar
Associate Secretary, CDMU
& Organising Secretary for
International Seminar on
Rational Use of Drugs

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Editorial

"Essential drugs are those that satisfy the health needs of the majority of the population; they should therefore be available at all the times in adequete amounts and is appropriate dosage forms".

The Use of Essential Drugs, TRS 825, WHO Geneva 1992.

In any civilized society, right to health is a fundamental right. Drugs, though not the be-all and end-all of solving health problems of the people, when judiciously used, can prove an indispensible tool to fight diseases, to protect, promote and restore health and to improve the quality of life. The provision of appropriate medicines of the right kind, quality and quantity, at affordable price, should therefore be a central concern for any government. It is unfortunate that even after about half a century has elapsed since Independence, the Government of India is yet to show its commitment in this regard. In the absence of a 'true' control over registration, promotion and sales of medicines in the country, the profiteering interest of the industry have greatly dominated over the interests of the ailing people. The lack of commitment and concern on the part of the government has become more obvious with the recently announced Drug Policy (1994).

The single most significant obstacte towards 'rational use of drugs'in India is perhaps the existence of the 'pharmaceutical jungle'. Countless number of formulations, a vast majority of which are absurd, unscientific or hazardous, do exist in the market, while majority of the people do not have access to the drugs they need most. Therefore, the foremost step in any attempt to 'rationalise' medicinal drug use in the country should be through upholding the essential drugs concept. The concept was evolved by the WHO keeping in view the primary responsibility of the State of ensure, utilizing its limited resources, the availability of the minimum number of drug needed to cater the health needs of majority of its population.

Many NGO's in India, like Voluntary Health Association of India, Community Development Medicinal Unit etc., some professional societies like India Pharmacological Society and a few state governments like Governments of West Bengal

and Delhi have prepared the essential drugs lists (EDL) and have been trying to implement the same in their jurisdiction. Nevertheless, the Government of India has not yet prepared a national EDL. The Inernational Seminar on Rational Use of Drugs held at Siliguri in April 22-24, 1995, took up the task of preparing an Essential Durgs List (EDL) for India based on the WHO guidelines. The Seminar utilized the experience and expertise of the international experts who attended the same, in producing the graded EDL through a consensus approach. It is hoped that this list would be impressive enough to the health, legislators and medical practitioners in India for its acceptance and adoption. The Part I of this manual contains the EDL prepared in Seminar.

It must however be remembered that preparing and adopting an EDL is only the first step and a committed action programme for its implementation must follow.

The Seminar also provided the platform for the national and international experts to analyse and assess the global drug situation vis-a-vis that in India and to resolve and suggest steps towards improving the same.

A selection of papers by some distinguished experts focussing the theme of rational use of drugs, discussed in or arising from the Seminar are published in the Part II of this volume.

We sincerely look forward for a healthier use of medicines in India.

Proceedings of the International Seminar on Rational Use of Drugs : A report

A Concerted Effort :

An International Seminar, jointly organized by Community Development Medicinal Unit (CDMU), International Organization of Consumers' Union (IOCU) and Rational Drug Campaign Committee in collaboration with Voluntary Healthy Association of India, All India Drug Action Network, Christian Medical Association, West Bengal Voluntary Health Association, North Bengal University, Jadavpur University, Paschim Banga Vigyan Mancha, Indian Medical Association, Association of Health Service Doctors, West Bengal and many organisations engaged in promotion of health and rational drug use was held at Siliguri, West Bengal, India from 22-24 April, 1995. The Seminar was attended by representatives from six countries, namely Australia, Philippines, Malaysia, Bangladesh, USA and India.

The Theme :

"Right to essential drugs at affordable price for better health - a consensus approach" - was the theme of the Seminar that aimed at preparing a consensus list of essential drugs (EDL) for India, and to develop an action programme for its implementation. A total of 43 experts and international and national delegates attended the meeting.

The Inaugural Session :

The meeting was inaugurated by the Hon'ble Health Minister, Govt. of West Bengal, Mr. Prasanta Sur. He expressed the necessity of updated drug information and monitoring system of the medical profession, and urged upon an active campaign for promotion of rational use of drugs. He also expressed serious concern about the adverse impact on India of the GATT agreement, and the recent modification of the Drug Price Control Order (DPCO), which he feared, might flood the country with inessential drugs of high price and profit. Mrs. Chhaya Bera, Minister of State, Dept. of Health & Family Welfare, Govt. of West Bengal, observed that the new DPCO will affect at least 100 critical drugs needed in the national health programme for eradication of endemic diseases in the country. Refering to a current survey, she said that 70% of drugs prescribed have no proven clinical rationale. Even the latest World Bank survey reveals that the general public are being unnecessarily drugged, she informed.

Speaking on the occasion, Dr. K. Balasubramaniam of IOCU lamented that India still did not have an EDL, and had barely managed to come forward with a National Drug Policy and an extremely complex DPCO. Use of numerous drugs that were banned in several developed and developing countries was still continuing in India, and in some instances, the Drug Controller of India was preparing for undertaking clinical trials afresh in order to attesting their worth, said Dr. Balasubramaniam.

Dr. M.J. George, the WHO representative appreciated that the Seminar was novel in its idea, since it was trying to concurrently address several issues of political advocacy, education and awareness, all in relation to drug use. He assured that the WHO would be happy to extend technical and financial support to all such efforts.

Ms. Mary Murrary, an expert from Australia, expressed that India possessed a great potential for an ideal health care system in the world. It was important to involve academicians, people from the industry, medical practitioners, and consumers to work together for a rational and effective drug policy, she commented.

Dr. Glen Miller of Mennonite Central Committee wished that the Seminar would contribute positively to promote health care by maximizing people's access to essential drugs.

The Technical Session :

Inaugurating the technical session of the Seminar, Dr. K. Balasubraniam from IOCU placed his paper on the impact of the proposed globalization of health care. He detailed that in the third world countries, a large amount of erosion has taken place in the real wages of people, following the declining GDP. The burden of loans from the 'fund-bank system' has primarily affected the health care, the cost of which has escalated to such an extent that modern medication has gone out of reach of more people in the low income bracket. He expressed that while preparing the EDL, one should be careful to save the national wealth and should cater to the needs of the large section of people.

Dr. Amit Sengupta from Delhi Science Forum, criticized that the national policies were being dictated by the World Bank and the IMF, and as a result, investment on health was flowing from 'where it is needed to where it is more commercially profitable'. The so-called "safety net" system from the world experience showed that it had failed to maintain vast sections of people at the minimum survival level. Detailing the drug availability situation in the country, he explained how the government has consciously ignored recommendations of several committees, and was making the country dependent on procuring drugs, including even the ORS from the multinationals. The existing health care system in the country had become predominantly biased towards profit-generation of the industry, he reiterated.

Mr. Amitava Guha of FMRAI (Federation of Medical and Sales Representatives Association of India) narrated that the Indian Patent regime as envisaged by the new WTO, would severely cripple the self-reliant pharmaceutical industry in India, and make the country largely import-dependent. As a result, availability of drugs at cheaper costs, would gradually become a remote possibility. He was strongly critical that the government was extending liberalization measures even beyond the expectation of WTO authorities. This would cause more influx of irrational and hazardous drugs, and take away the government support for the poor, he feared.

Dr. N.C. Banerjee, Chairman, Rational Drug Campaign Committee, expressed deep concern on the sale of nearly 70,000 for mulations in the country, which he feared might even go up following government's liberalization policy. He expressed his doubts that "health for all" could be achieved by 2000 A.D.

The Drug Controller of West Bengal, Dr. N.C. Bagchi, informed of his effort to improve the quality of drugs produced in this part of the country, and admitted the inadequacy of the existing law to tackle/punish violators. He also informed, that the Central Government had prepared in November '94, a list of drugs for procurement by government hospitals, and the other central institutions, which contained irrational combination of 187 brands of analgesics, and 230 types of tonics, and vitamins.

Dr. Mira Shiva from Voluntary Health Association of India (VHAI) stressed the urgent need for a rational drug policy. She observed that a crisis in health care system had developed due to shift from emphasizing on primary health care system to the commoditization of the entire health care facilities. Despite being one of the most important breakthrough in modern therapeutics in recent times, the ORT has not yet found its rightful place in India; a large number of irrational ORT formulations are still being allowed to flood the market, the nutrition supplementation programmes are being badly neglected. Diseases like tuberculosis, malaria etc. are resurgent at alarming magnitude. At this juncture, the

liberalisation policy recommended by the Govt. of India in the area of health and pharmaceuticals, would only worsen the situation further and add to the suffering of the nation, Dr. Shiva reiterated.

Dr. Quasem Chowdhury of Ganasasthya a Kendra, Bangladesh, stressed that a national health policy could not be effective without an EDL which simultaneously warrants a change in medical education. Sharing his experience in the Bangladesh EDL movement, he emphasized the need of involving the medical fraternity in campaigning for a rational health and drug policy for India. There should be an EDL, he said, not only for the government health care facilities but for the private sectors also.

Dr. W.V. Rane, a noted activist in the rational drug movement in India demonstrated using various statistics, how the prices of essential drugs had increased out of proportion in recent years in India, and that the new DPCO would further escalate it. He gave examples to show that the same drug was being sold in widely different prices under different brand names.

Dr. P.K. Sarkar, Professor of Pharmacology, informed about the types of irrational and hazardous drugs freely available and sold in the country.

Dr. Anant Phadke, presented the findings of a drug utilization study undertaken by him under the auspices of Medico Friends Circle, Pune.

The technical session was coordinated and supervised by Prof. B.N. Nag, a reputed pharmacologist and champion of the rational drug movement India.

Drafting the EDL for India :

Parallel to the technical session, a team of experts, comprising of noted clinicians from different specialities, pharmacologists and medical sociologists was working for compilation of a draft of EDL; the activity was coordinated by Dr. S.K. Tripathi, a clinical pharmacologist. While preparing the list, similar efforts by different groups in the recent past were attended to with due importance. The draft EDL was placed in the plenary, on 23rd April, 1995. After a long debate and discussion, the Seminar developed a consensus EDL, which was prepared for different levels, eg., village health workers, primary health care units, district hospitals, multidisciplinary institutions etc.

Declaration on the EDL :

In preparing an Essential Drugs List (EDL) for India, the Seminar took cognizance of the WHO guidelines regarding EDL preparation and oriented its discussions in the perspective of the socio-economic and morbidity situations prevailing in India. The Seminar also considered different factors contributing to the health economics and the health care needs of the majority of the people of the country. The draft EDL as recommended by the Expert Committee was duly finalised after a consensus was reached through reassessment in an open house session. The consensus EDL, it was decided, would be utilized as a propaganda list, and would be used to propagate the concepts of essential drugs and their rational use. The Seminar decided to campaign for adoption of the list and to involve all fraternal sections engaged in rational drug movement in such campaign programme. It was demanded that the government should consider the list for ensuring adequate availability of these drugs at an affordable price, at the same time assuring good quality. The Seminar stressed that the Government should ensure production and distribution of these drugs giving priority for facilitating the role to be played by the public sector units. The Government should also ensure appropriate production-control machinery for encouraging and monitoring production of drugs in the EDL by the drug industry.

The Seminar strongly criticised the Government's decontrol and deregulatory steps in the name of the so-called liberalisaton's and demanded a strong price-control regime for essential drugs, enforce-

ment of code of drug procurement for all levels and provision for adequate funds for health expenditure by the Centre as well as by the individual State governments. The expert delegates strongly felt that the proposed change in Indian Patents Act, 1970 would hike the prices of drugs, do away with self-reliance in pharmaceutical industry and could not ensure availability of essential drugs at affordable price, rather provide more scope for the Indian market to be burdened with irrational, bannable and hazardous drugs. The Seminar demanded that the Government should develop appropriate machinery with sufficient power to enforce stringent punishment of the violators of drug laws and regulations. The drug control machinery must enforce immediate steps for weeding out all irrational and hazardous drugs forthwith.

With this declaration, the Seminar strongly urged upon the Government for adopting this consensus EDL duly prepared.

In pursuance of the demands, the Seminar decided mass signature campaign of various professionals, scientific groups, health/drug activists, and common people and to give a call to different organisations and people's representatives to extend help in this campaign and observe protest-day, in case the Government remains unresponsive. The Seminar also decided on developing cooperation among various organizations in different countries of South-East Asia and the Pacific region.

It was also suggested that a through review of the EDL should be done once every 2-3 years.

The Pledge :

The valedictory session marked the end of the three-day Seminar with a determined promise to perpetuate and sustain the fight to win people's right to essential drugs.

Part I

A Graded List of Essential Drugs for India

Expert Committee for Preparing an EDL for India

Members :

Professor B.N. Nag, Principal, N.R.S. Medical College, Calcutta-700 014, ***(Chairman).***

Dr. S.K. Tripathi, Associate Professor of Pharmacology, N.R.S. Medical College, Calcutta-700 014, ***Convener-Secretary.***

Professor B. Ekbal, Head of the Deptt. of Neurology, Medical College Hospital, Kottayam.

Professor P.K. Sarkar, Dept of Pharmacology, School of Tropical Medicine, Calcutta.

Professor J.S. Bapna, Dept of Pharmacology, Mulana Azad Medical College, New Delhi.

Professor Amitava Nandi, Dept of Protozoology, School of Tropical Medicine, Calcutta.

Dr. N.C. Banerjee, Chairman, Rational Drug Compaign Committee, and Advisor to the Health & Family Welfare Dept., Govt. of West Bengal, Calcutta.

Professor N.C. Bagchi, Director of Drugs Control, Govt. of West Bengal, Calcutta.

Dr. Mira Shiva, Head, Dept. Public Policy, VHAI, New Delhi.

Dr. W.V. Rane, Health Activist, Arogya Mitra Mondal, Pune.

Maj. Gen. S.B.D. Chaudhury, Chief Medical Officer, Goodricke Group Ltd, and Ex-Professor (Obst & Gyn), Armed Forces Medical College, Pune.

Dr. Anant Phadke, Medico Friend Circle, Pune.

Dr. Amit Sengupta, Delhi Science Forum, New Delhi.

Professor (Ms.) S. Chhabra, Head, Dept of Obst. & Gyn, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha.

Professor B.K. Gupta, Dept. of Pharmatechnology, Jadavpur University, Calcutta.

Mr. Amitava Guha, Secretary, Federation of Medical Representetives' Association of India, Calcutta.

Dr. B. Jacob, Community Development Medicinal Unit, Calcutta.

International Experts

Dr. K. Balasubramanium, Pharmacutical Adviser, Consumer International (CI), Penang, Malaysia.

Dr. Quasem Chowdhury, Gana Swasthya Kendra, Bangladesh.

Ms. Mary Murray, Commonwealth Dept. of Human Services & Health, Australia.

Ms. Beverly Snell, Victorian Medical Postgraduate Foundation, Australia.

Ms. Edelisa D. Carandang, National Drug Policy Bureau of Food & Drugs, Philippines.

WHO Representative

Dr. M.J. George, National Programme Officer (India), WHO, New Delhi.

A Graded List of Essential Drugs for India

As Proposed by the Expert Committee *at the International Seminar on Rational Use of Drugs* held during 22nd - 24th April, 1995 at Siliguri, India.

Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
1.	**Anaesthetics**					
1.1	*General anaesthetics and Oxygen*					
	Diazepam	Injection, 5mg/ml in 2ml ampoule		+	+	+
	Ether, anaesthetic	Inhalation			+	+
	Halothane	Inhalation			+	+
	Nitrous oxide	Inhalation			+	+
	Oxygen (medical gas)	Inhalation		+	+	+
	Thiopental	Power for injection 0.5g 0.5g, 1.0g (sodium salt) in ampiule.			+	+
	Ketamine	Injection, 50mg (as hydrochloride)/ml in 10ml vial			+	+
1.2	*Local anaesthetics*					
	Bupivacaine	Injection, 0.5% (hydrochloride) in vial. In case of spinal anaesthesia to be mixed with 7.5% glucose solution.			+	+
	Lidocaine	Injection, 1%, 2% (hydrochloride) in vial.		+	+	+
		Injection, 1%, 2% (hydrochloride) plus epinephrine 1:200000 in vial.		+	+	+
		Injection for spinal anaesthesia, 5% (hydrochloride) in 2ml ampoule. In case of spinal anaesthesia, to be mixed with 7.5% glucose solution.			+	+
		Topical jelly, 2-4% (hydrochloride)		+	+	+
		Dental cartridge, 2% (hydrochloride) plus epinephrine 1: 80000			+	+
1.3	*Preoperative medications*					
	Atropine	Injection 1mg (sulphate) in 1ml ampoule.		+	+	+
	Diazepam	As under 1.1		+	+	+
	Morphine	Injection 10mg (sulphate or hydrochloride) in 1ml ampoule.			+	+
	Promethazine	Injection (hydrochloride) 2.5% in 2ml ampoule.			+	+
1.4	*Muscle relaxants (peripherally acting) and anticholinesterases*					
	Gallamine	Injection 40mg (triethiodide) /ml in 2ml ampoule.			+	+
	Neostigmine	Injection 2.5mg (methylsulfate) in 1ml ampoule.			+	+
	Suxamethonium	Injection 50mg (chloride)/ml in 2ml ampoule.			+	+
	Vecuronium bromide	Powder for injection 10mg in vial			+	+
2.	**Analgesics, antipyretics, NSAID's and antigout and antimigraine agents.**					
2.1	*Non-opioid analgesies*					
	Acetylsalicylic acid	Tablet 500mg (scored for one-fourth)	+	+	+	+

[V = Village Health Worker; P = Primary Care Hospital e.g. Primary Health Centre; S = Secondary Care Hospital e.g. Sub-Divisional and District Hospitals with limited specialist care facilities; T = Tertiary Care Hospital e.g. UG & PG Teaching Hospitals]

Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
	Ibuprofen	Table 2000mg.		+	+	+
	Indomethacin	Capsule or tablet 25mg.			+	+
	Paracetamol	Tablet 500mg. (secored for one-fourth) Syrup, 125mg/5ml.	+	+	+	+
2.2.	*Opioid analgesics*					
	Codeine	Tablet 30mg (phosphate)		+	+	+
	Morphine	As under 1.3			+	+
	Pethidine	Injection, 50mg (hydrochloride) in 1ml ampoule		+	+	+
2.3	*Antigout agents*					
	Allopurinol	Tablet 100mg.			+	+
	Colchicine	Tablet 500mg.			+	+
2.4	*Antimigraine agents*					
	Acetylsalicylic acid	As under 2.1	+	+	+	+
	Ergotamine	Tablet 2mg (tartrate)			+	+
	Paracetamol	Tablet 500mg (scored)	+	+	+	+
	Propranolol	Tablet 20mg (scored) (hydrochloride)			+	+
3.	**Antiallergics**					
	Chlorpheniramine	Tablet 4mg. (hydrogen maleate)		+	+	+
		Injection 10mg (hydrogen maleate) in 1ml ampoule.		+	+	+
	Dexamethasone	Tablet 500mcg, 4mg.		+	+	+
		Injection 4mg (as sodium phosphate) in 1ml. ampoule		+	+	+
	Epinephrine	Injection, 1mg (as hydrochloride) in 1ml ampoule.	+	+	+	
	Hydrocortisone	Powder for injection, 100 mg (as sodium succinate) in vial.			+	+
	Prednisolone	Tablet, 5mg.		+	+	+
4.	**Antidotes and other drugs used in poisonings**					
4.1	*General*					
	Activated charcoal	Powder		+	+	+
4.2	*Specific*					
	Atropine	As under 1.3		+	+	+
	Deferoxamine	Powder for injection, 500mg (mesilate) in vial.			+	+
	Dimercaprol	Injection in oil, 50mg/ml in 2ml ampoule				+
	Methylene blue (Methylthioninium chloride)	Injection 10mg/ml in 10ml ampoule.			+	+
	Naloxone	Injection 400mg (hydrochloride) mcg in 1ml ampoule.		+	+	+
	D-Penicillamine	Capsule or tablet 12.5 mg-250mg			+	+
5.	**Antiepileptics**					
	Carbamazepine	Tablet 100mg, 200mg (both scored), Syrup 100mg/5ml.		+	+	
	Diazepam	As under 1.1 (intravenous or rectal)		+	+	+
	Ethosuximide	Capsule or tablet 250mg, 100mg (sodium salt)			+	+
		Syrup 250mg/5ml.			+	+

[V = Village Health Worker; P = Primary Care Hospital e.g. Primary Health Centre; S = Secondary Care Hospital e.g. Sub-Divisional and District Hospitals with limited specialist care facilities; T = Tertiary Care Hospital e.g. UG & PG Teaching Hospitals]

Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
	Phenobarbital	Tablet 30mg, 60mg (both scored)			+	+
		Elixir 15mg/5ml			+	+
	Phenytoin	Capsule or tablet 25mg.			+	+
		100mg (sodium salt)			+	+
		Suspension 125mg/5ml.			+	+
		Injection 50mg (sodium salt)/ml in 5ml vial			+	+
	Valproic acid	Enteric coated tablet, 200mg, 500mg (sodium salt)			+	+
		Syrup 200mg/5ml. (sodium salt)			+	+
6.	**Antiinfective drugs**					
6.1	*Anthelminthics*					
	Mebendazole	Tablet 100mg.			+	+
		Suspension 100mg/5ml.		+	+	+
	Niclosamide	Chewable tablet 500mg		+	+	+
	Praziquantel	Tablet 150mg, 600mg.				+
	Pyrantel	Chewable tablet 250mg (as embonate)		+	+	+
		Suspension 50mg (as embonate)/5ml		+	+	+
	Diethylcarbamazine	Tablet 50mg (dihydrogen citrate)		+	+	+
6.2	*Antibacterials*					
6.2.1	Penicillins					
	Amoxicillin	Capsule or tablet, 250mg, 500mg (anhydrous)		+	+	+
		Powder for oral suspension 125mg (anhydrous)/5ml		+	+	+
	Ampicillin	Powder for injection, 500mg (as sodium salt) in vial.			+	+
	Benzathine benzyl penicillin	Power for injection 1.44 g benzylpenicillin (2.4 million IU) in 5ml vial.		+	+	+
	Benzylpenicillin	Power for injection 600mg (= 1 million IU) 3 G (= 5 million IU) (as sodium or potassium salt) in vial.		+	+	+
	Cloxacillin	Capsule 500mg (as sodium salt)			+	+
		Powder for oral solution 125mg (as sodium salt)/5ml.			+	+
		Powder for injection, 500mg (as sodium salt) in vial.				+
	Phenoxymethylpenicillin	Tablet 250mg (as potassium salt)		+	+	+
		Powder for oral suspension 250 mg (as potassium salt)/5ml.		+	+	+
	Carbenicillin	Powder for injection 1g, 5g (as disodium salt)				+
	Procaine benzyl penicillin	Powder for injection 1 g (=1 million IU) 3 g (= 3 million IU)		+	+	+
6.2.2	*Other antibacterials*					
	Cefaclor	Capsule 250mg, 500mg			+	+
		Powder for suspension 125mg/5ml.			+	+
	Cefotaxime	Powder for injection 500mg, 1g, 2g (as sodium salt) in vials.				+
	Ceftazidime	Powder for injection, 500mg, 1g, 2g (pentahydrate) in vials.				+
	Chloramphenicol	Capsule 250mg		+	+	+
		Oral suspension 150mg (as palmitate)/5ml.		+	+	+
		Powder for injection, 1g (as sodium succinate) in vial.		+	+	

[V = Village Health Worker; P = Primary Care Hospital e.g. Primary Health Centre; S = Secondary Care Hospital e.g. Sub-Divisional and District Hospitals with limited specialist care facilities; T = Tertiary Care Hospital e.g. UG & PG Teaching Hospitals]

Therapeutic Category and Drug	Dosage Form and Strength	Usage Level V	P	S	T
Erythromycin	Capsule or tablet 250mg (as stearate or ethylsuccinate)	+	+	+	
	Powder for oral suspension, 125mg (as stearate or ethylsuccinate).		+	+	+
	Powder for injection 500mg (lactobionate) in vial.			+	+
Gentamicin	Injection 10mg, 40mg (as sulfate).ml in 2ml vial.			+	+
Metronidazole	Tablet 200mg, 400mg		+	+	+
	Injection 500mg in 100ml vial			+	+
	Oral suspension 200mg (as benzoate)/5ml.		+	+	+
Cotrimoxazole (Sulfamethoxazole+ Trimethoprim)	Tablet 100mg+20mg, 400mg+80mg	+	+	+	+
	Oral suspension 200mg+400mg/5ml	+	+	+	+
Doxycycline	Capsule or tablet 100mg (as hyclate)		+	+	+
	Powder for injection 100mg (as hyclate) in ampoule.			+	+
Ciprofloxacin	Tablet 250mg (hydrochloride)		+	+	+
Trimethoprim	Tablet 100mg, 200mg		+	+	+
Pyrimethamine	Tablet 25mg.			+	+
6.2.4 *Topical preparations used in bacterial infections of skin*					
Gentian violet	Aqueous solution 0.5%, Tincture 0.5%	+	+	+	+
Silver sulfadiazine	Cream 1%	+	+	+	+
Neomycin+ Bacitracin	Ointment 5mg+500 IU/g		+	+	+
6.2.5 *Drugs for eye infection (bacterial)*					
Gentamicin	Solution (eye drops) 0.3%.			+	+
Tetracycline/chloramphenicol	Eye ointment 1% (hydrochloride)	+	+	+	+
6.2.6 *Antileprosy drugs*					
Clofazimine	Capsule 50mg, 100mg			+	+
Dapsone	Tablet 50mg, 100mg			+	+
Rifampicin	Capsule or tablet 150mg, 300mg			+	+
6.2.7 *Antituberculosis drug*					
Ethambutol	Tablet 100-400 mg (hydrochloride)			+	+
Isoniazid	Tablet 100-300mg			+	+
Pyrazinamide	Tablet 500mg			+	+
Rifampicin	As under 6.2.3			+	+
Streptomycin	Powder for injection 0.75g as sulfate in vial			+	+
Thioacetazone	Tablet 50mg, 150mg			+	+
6.3 *Antifungal drugs*					
Amphotericin B	Powder for injection 50mg in vial				+
Griseofulvin	Capsule or tablet 125mg, 250mg		+	+	+
Ketoconazole	Tablet 200mg.			+	+
	Oral suspension 100mg/5ml			+	+
Nystatin	Tablet 100000 IU, 500000 IU			+	+
	Oral suspension 100000 IU/ml			+	+
	Cream (dermal application) 100000 IU/g		+	+	+

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Therapeutic Category and Drug	Dosage Form and Strength	Usage Level V	P	S	T
Clotrimazole	Cream 1%		+	+	+
	Dusting powder 1%		+	+	+
Benzoic acid + Salicyclic acid	Ointment or cream 6% + 3%	+	+	+	+
Miconazole	Ointment or cream 2% (nitrate)	+	+	+	+
6.4 *Antiprotozoal drugs*					
6.4.1 *Antiamoebic and antigiardiasis drugs*					
Diloxanide	Tablet, 500mg (furoate)		+	+	+
Metronidazole	Tablet 200mg, 400mg	+	+	+	+
	Oral suspension 200mg (as benzoate)/5ml.	+	+	+	+
6.4.2 *Antileishmaniasis drugs*					
Pentavalent antimonials					
Pentamidine (aromatic diamidine)	Powder for injection 200mg (isetionate) in vial			+	+
6.4.3 *Antimalarials*					
Chloroquine	Tablet 150mg (as sulphate or phosphate)	+	+	+	+
	Syrup 50mg/ml (as sulphate or phosphate)		+	+	+
	Injection 40mg/ml (as sulphate)			+	+
Primaquine	Tablet 7.5mg (as diphosphate)		+	+	+
Quinine	Tablet 300mg (as sulphate)			+	+
	Injection 300mg (as dihydrochloride)/ml in 2ml ampoule			+	+
Sulphadoxine + Pyrimethamine	Table 500mg + 25mg			+	+
Doxycycline	As under 6.2.2.				
6.5 *Scabicide and Pediculicide*					
Benzyl benzoate	Lotion, 25%		+	+	+
7. Antineoplastic drugs					
7.1 *Immunosuppressant drugs*					
Azathioprine	Tablet 50mg				+
	Powder for injection 100mg (as sodium salt) in vial.				+
Cyclosporine	Capsule, 25mg				+
	Concentrate for injection, 50mg.ml in 1ml ampoule				+
7.2 *Cytotoxic drugs*					
Bleomycin	Powder for injection, 15mg (as sulfate) in vial				+
Cisplatin	Powder for injection 10mg, 50mg in vial.				+
Cyclophosphamide	Tablet, 25mg				+
	Powder for injection, 500mg in vial			+	+
Cytarabine	Powder for injection, 100mg in vial			+	+
Dactinomycin	Powder for injection, 500mcg in vial.			+	+
Doxorubicin	Powder for injection, 10mg, 50mg (hydrochloride) in vial.				+
Etoposide	Capsule, 100mg, Injection, 20mg/ml in 5ml ampoule				+
Fluorouracil	Injection, 50mg/ml in 5ml ampoule				+
Mercaptopurine	Tablet, 50mg.				+
Methotrexate	Tablet, 2.5mg (as sodium salt)				+
	Powder for injection, 50mg (as sodium salt) in vial.				+

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Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
	Procarbazine	Capsule, 50mg (as hydrochloride)				+
	Vinblastine	Powder for injection, 10mg (sulfate) in vital.				+
	Vincristine	Powder for injection, 1mg, 5mg (sulfate) in vial			+	+
7.2.1	*Complementary drug*					
	Calcium folinate	Tablet, 15mg Injection, 3mg/ml in 10ml ampoule				
7.3	Hormones and antihormones					
	Dexamethasone	Tablet, 500mcg, 4mg				+
		Injection, 4mg (as sodium phosphate) in 1ml ampoule				+
	Ethinylestradiol	Tablet, 50mcg				+
	Prendisolon	Tablet, 5mg			+	+
		Injection, 20mg, 25mg (as sodium phosphate or sodium succinate) in vial				+
	Tamoxifen	Tablet, 10mg, 20mg (as citrate)				+
8.	**Anti-parkinsonism drugs**					
	Trihexyphenidyl	Tablet (scored), 2mg, 5mg (as hydrochloride)			+	+
	Levodopa + Carbidopa	Tablet 100mg + 10mg, 250mg + 25mg			+	+
9.	**Drugs affecting the blood**					
9.1	*Antianaemia drugs*					
	Ferrous salt	Tablet, equivalent to 60mg iron		+	+	+
		Oral solution, equivalent to 25mg iron (as sulfate)/ml		+	+	+
	Ferrous salt + Folic acid	Tablet 60mg (iron)+ 250mcg	+	+	+	+
	Folic acid	Tablet 1mg, 5mg			+	+
		Injection 1mg (as sodium salt) in 1ml ampoule			+	+
	Iron dextran	Injection, equivalent to 50 mg iron/ml in 2ml ampoule			+	+
9.2	*Drugs affecting coagulation*					
	Heparin	Injection, 1000 IU/ml. 5000 IU/ml. 20,000 IU/ml in 1ml ampoule			+	+
	Phytomenadione	Tablet 10mg.		+	+	+
		Injection 10mg/ml in 5ml ampoule		+	+	+
	Protamine sulfate	Injection 10mg/ml in 5ml ampoule			+	+
	Warfarin	Tablet 1mg, 2mg, 5mg (sodium salt)			+	+
10.	**Plasma substitutes and blood products :**					
	Dextran 70	Injectable solution 6%			+	+
11.	**Cardiovascular drugs**					
11.1	*Antianginal drugs*					
	Glyceryl trinitrate	Tablet (sublingual) 500mcg			+	+
	Isosorbide dinitrate	Tablet (sublingual) 5 mg			+	+
	Nifedipine	Capsule or tablet 10mg			+	+

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Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
	Propranolol	Tablet 40mg (hydrochloride) (scored)			+	+
		Injection 1mg (hydrochloride) /ml in 1ml ampoule.			+	+
	Atenolol	Tablet 50mg, 100mg.			+	+
11.2	*Antidysrhythmic drugs*					
	Lidocaine	Injection 20mg (hydrochloride) /ml in 5ml ampoule				+
	Propranolol	As under 12.1			+	+
	Verapamil	Tablet 40mg, 80mg (hydrochloride)			+	+
		Injection 2.5mg (hydrochloride)/ml in 2ml ampoule.			+	+
	Quinidine	Tablet 200mg (sulfate)			+	+
11.3	*Antihypertensive drugs*					
	Hydralazine	Tablet 25mg. 50mg (hydrochloride)		+	+	+
		Power for injection, 20mg (hydrochloride) in ampoule			+	+
	Hydrochlorothiazide	Tablet, 25mg		+	+	+
	Furosemide	Tablet, 40mg		+	+	+
	Nifedipine	As under 11.1		+	+	+
	Propranolol	Tablet 40mg, 80mg (hydrochloride)		+	+	+
	Atenolol	As under 11.1		+	+	+
	Enalapril	Tablet 25mg (scored)		+	+	+
	Methyldopa	Tablet 250mg			+	+
	Reserpine	Tablet 100mcg, 250mcg		+	+	+
	Sodium nitroprusside	Powder for infusion 50mg in ampoule				+
11.4	*Cardiac glycosides*					
	Digoxin	Tablet 62.5mcg, 250mcg			+	+
		Injection 250mcg/ml in 2ml ampoule			+	+
11.5	*Drugs used in vascular shock*					
	Dopamine	Injection 40mg (hydrochloride) /ml in 5ml ampoule			+	+
11.6	*Antithrombotic drugs*					
	Acetylsalicylic Acid	Tablet 50mg.			+	+
	Streptokinase	Powder for injection 100000 IU in vial				+
12.	**Dearmatological drugs**					
12.1	*Antifungal drugs (topical)*					
	See section 6.3					
12.2.	*Antiinfective drugs*					
	See section 6.2.4					
12.3	*Anti-inflammatory and antipruritic drugs*					
	Betamethasone	Ointment 0.1% (as valerate)			+	+
	Calamine	Lotion	+	+	+	
	Hydrocortisone	Ointment 1% (acetate)			+	+
12.4	*Keratoplastic and keratolytic agents*					
	Benzoyl peroxide	Lotion or cream 5%				+
	Coal tar	Solution, topical 5%				+

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Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
	Dithranol	Ointment 0.1-2%				+
	Podophyllum resin	Solution, topical 10-25%			+	+
	Salicylic acid	Solution, topical, 5%			+	+
12.5.	Scabicides See section 6.5					
13.	**Diagnostic agents**					
13.1	*Ophthalmic drugs*					
	Fluorescein	Eye drops, 1% (sodium salt)		+	+	+
	Tropicamide	Eye drops, 0.5%		+	+	+
13.2	*Immunologicals*					
	Tuberculin (PPD)	Injection		+	+	+
13.3	*Radiocontrast media*					
	Amidotrizoate	Injection 140-420mg iodine (as sodium or meglumine salt) /ml in 20ml ampoule			+	+
	Barium sulfate	Aqueous suspension			+	+
	Iopanoic acid	Tablet 500mg			+	+
	Propyliodone	Oily suspension, 500-600mg/ ml in 20ml ampoule				+
	Meglumine	Injectable solution 5-8 g iodine (as meglumine salt) 100-250ml.				+
	Iohexol	Injection 140-350 mg iodine/ml in 100ml ampoule.				+
14.	**Disinfectants and antiseptics**					
14.1	*Antiseptics*					
	Chlorhexidine	Solution 5% (digluconate) for dilution.		+	+	+
	Hydrogen peroxide	Solution 3%		+	+	+
	Iodine	Solution 2.5%		+	+	+
14.2	*Disinfectants*					
	Calcium hypochlorite	Powder (70% available chlorine) for solution.		+	+	+
	Glutaral	Solution, 2%			+	+
15.	**Diuretics**					
	Furosemide	Tablet 40mg		+	+	+
		Injection 10mg/ml in 2ml ampoule		+	+	+
	Hydrochlorothiaride	Tablet 25mg, 50mg		+	+	+
	Mannitol	Injectable solution, 10%, 20%			+	+
	Spironolactone	Tablet, 25mg			+	+
16.	**Gastrointestinal drugs**					
16.1	*Antacids and other antiulcer drugs*					
	Dried Aluminium hydroxide gel + Magnesium hydroxide	Chewable tablet 250mg	+	+	+	+
		Oral suspension 250mg+250mg/5ml		+	+	+
	Ranitidine	Tablet 150mg (as hydrochloride)			+	+
		Injection 25mg (as hydrochloride)/ml in 2ml ampoule				+

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Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
16.2	*Antiemetic drugs*					
	Metoclopramide	Tablet 10mg (as hydrochloride)		+	+	+
		Injection 5mg (as hydrochloride) /ml in 2ml ampoule			+	+
	Promethazine	Injection 25mg (hydrochloride) /ml in 2ml ampoule			+	+
16.3	*Antihaemorrhoidal drugs*					
	Compound topical preparation with a corticosteroid (e.g. betamethasone vale, rate 0.05%) a local anaesthetic (e.g. lignocaine hydrochloride 2.5%), and a sympathomimetic (e.g. phenylephrine hydrochloride 0.1%)	Ointment or suppository		+	+	+
16.4	*Anti-inflammatory drugs*					
	Hydrocortisone	Suppository 25mg (acetate)			+	+
	Sulfasalazine	Tablet, 500mg			+	+
16.5	*Antispasmodic drugs*					
	Atropine	Tablet, 1mg (sulfate)		+	+	+
		Injection 1mg (sulfate) in 1ml ampoule		+	+	+
16.6	*Cathartic drugs*					
	Bisacodyl	Tablet, 5mg.		+	+	+
		Suppository (rectal), 10mg		+	+	+
16.7	*Drugs used in diarrhoea*					
16.7.1	*Oral rehydration agent*					
	Oral rehydration salts (for glucose -electrolyte solution)	Powder 27.9g/1	+	+	+	+
	Components	g/1				
	Sodium chloride	3.5				
	Trisodium citrate dihydrate	2.9				
	potassium chloride	1.5				
	Glucose	20.0				
16.7.2	*Symptomatic antidiarrhoeal*					
	Codeine	Tablet 30mg (phosphate)		+	+	+
17.	**Hormones, other endocrine drugs and contraceptives**					
17.1	*Adrenal hormones and synthetic substitutes*					
	Dexamethasone	Tablet, 500mcg,			+	+
		Injection 4mg (as sodiumphosphate) in 1ml ampoule		+	+	+
	Hydrocortisone	Powder for injection, 100mg (as sodium succinate) in vial		+	+	+
	Prednisolone	Tablet 1mg, 5mg		+	+	+
	Fludrocortisone	Tablet 100mcg (acetate)				+
17.2	*Androgens*					
	Testosterone	Injection 200mg (enanthate) in 1ml ampoule				+
17.3	*Contraceptives*					
17.3.1	*Hormonal contraceptives*					
	Ethinylestradiol + Levonorgestrel	Tablet 30mcg+ 150mcg, 30mcg+250mcg		+	+	+

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Therapeutic Category and Drug		Dosage Form and Strength	Usage Level V	P	S	T
	Ethinylestradiol + Norethisterone	Tablet 35mcg+1.0mg		+	+	+
	Norethisterone	Tablet 350mcg		+	+	+
17.3.2	*Intrauterine devices*					
	Copper-containing devices	Copper T		+	+	+
17.3.3	*Barrier devices*					
	Condoms			+	+	+
	Diaphragms with spermicide (nonoxinol)		+	+	+	
17.4	*Estrogens*					
	Ethinylestradiol	Tablet 50mcg		+	+	+
17.5	*Insulins and other antidiabetic agents*					
	Insulin injection	Injection 100 IU/ml in 10ml (soluble) vial		+	+	+
	Intermediate-acting Insulin	Injection 100 IU/ml in 10ml vial (as insulin zinc-suspension or isophane insulin)			+	+
	Glibenclamide	Tablet 5mg			+	+
17.6	*Ovulation inducers*					
	Clomifene	Tablet 50mg (citrate)				+
17.7	*Progestogens*					
	Norethisterone	Tablet 5mg			+	+
17.8	*Thyroid hormones and antithyroid drugs*					
	Levothyroxine	Tablet (as sodium salt) 50mcg, 100mcg			+	+
	Potassium iodide	Tablet 60mg			+	+
	Propylthiouracil	Tablet 5mg			+	+
18.	**Vaccines and sera**					
18.1	*Sera and immunoglobulins*					
	Anti-D immunoglobulin (human)	Injection 250mcg in single dose vial		+	+	+
	Antitetanus immunoglobulin (human)	Injection 500 IU in vial				+
	Antivenon sera	Injection		+	+	+
	Diphtheria antitoxin	Injection 10000 IU, 20000 IU in vial				+
	Immunoglobulin, normal (human)	Injections				+
	Rabies immunoglobulin	Injection 150 IU/ml in via				+
18.2	*Vaccines*					
18.2.1	*For universal immunization*					
	BCG vaccine	Injection		+	+	+
	DPT vaccine	Injection		+	+	+
	DT vaccine	Injection		+	+	+
	MMR vaccine	Injection		+	+	+
	Measles vaccine	Injection		+	+	+
	Oral polio vaccine	Oral solution		+	+	+
	Tetanus vaccine	Injection		+	+	+

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Therapeutic Category and Drug	Dosage Form and Strength	Usage Level V	P	S	T
18.2.2 *For specific groups of individuals*					
Hepatitis B vaccine	Injection			+	+
Rabies vaccine	Injection (human diploid)			+	+
Typhoid vaccine	Injection			+	+
19. Drugs used in myasthenia gravis					
Neostigmine	Tablet 15mg (bromide)				+
20. Ophthalmological preparations					
20.1 *Anti-inflammatory drugs*					
Dexamethasone	Eye drop 0.5%			+	+
20.2 *Local anaesthetics*					
Tetracaine	Eye drop 0.5% (hydrochloride)				+
20.3 *Miotics and antiglaucoma drugs*					
Acetazolamide	Tablet 250mg				+
Pilocarpine	Eye drop 2%, 54% (hydrochloride or nitrate)				+
Timolol	Eye drop 0.25%, 0.5% (maleate)				+
20.4 *Mydriatics*					
Atropine	Eye drop 0.1%, 0.5%, 1% (sulfate)				+
Epinephrine	Eye drop 2% (as hydrochloride)				+
21. Oxytocics and tocolytics					
Ergometrine	Tablet 200mcg (hydrogen maleate)		+	+	+
	Injection 200mcg (hydrogen maleate) in 1ml ampoule		+	+	+
Oxytocin	Injection 10 IU in 1ml ampoule		+	+	+
Salbutamol	Tablet 4mg (as sulfate)		+	+	+
	Injection 50mcg (as sulfate)/ml in 5ml ampoule		+	+	+
22. Peritoneal dialysis solution					
Intraperitoneal dialysis solution (of appropriate composition)	Parenteral solution				+
23. Psychotherapeutic drugs					
Amitriptyline	Tablet 25mg (hydrochloride)				+
Chlorpromazine	Tablet 100mg (hydrochloride)			+	+
	Syrup 25mg (hydrochloride)/5ml				+
	Injection 25mg (hydrochloride) /ml in 2ml ampoile			+	+
Diazepam	Tablet 2mg, 5mg (scored)		+	+	+
Fluphenazine	Injection 25mg (decanoate o enanthate) in 1ml ampoule				+
Haloperiodol	Tablet 2mg, 5mg				+
	Injection 5mg in 1ml ampoule				+
Lithium carbonate	Capsule or tablet 300mg (scored)				+

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Therapeutic Category and Drug	Dosage Form and Strength	Usage Level V	P	S	T
24.	**Drugs acting on the respiratory tract**				
24.1	*Antiasthma drugs*				
Aminophylline	Injection 25mg/ml in 10ml ampoule.		+	+	+
Beclomethasone	Inhalation (aerosol) 50mcg (dipropionate) per dose			+	+
Epinephrine	Injection 1ml (as hydrochloride) in 1ml ampoule			+	+
Salbutamol	Tablet 2mg, 4mg (as sulfate).		+	+	+
	Inhalation (aerosol) 100mcg (as sulfate) per dose.				
	Syrup 2mg (as sulfate)/5ml.		+	+	+
	Injection 50mcg (as sulfate) /ml in 5ml ampoule			+	+
	Respiratory solution for use in nebulizers, 5mg (as sulfate) /ml				+
Theophylline	Tablet 100mg, 200mg		+	+	+
Sodium cromoglycate	Inhalation (aerosol) 20mg per dose			+	+
24.2	*Antitussive drugs*				
Codeine	Tablet 10mg (phosphate)		+	+	+
25.	**Solution for correcting water, electrolyte and acid-base imbalance**				
25.1	*Oral rehydration agents*				
Oral rehydration salts (for glucose -electrolyte solution)	See section 16.7.1 for composition	+	+	+	+
Potassium chloride	Powder for oral solution			+	+
25.2	*Parenteral solutions*				
Glucose	Injection solution 5% isotonic, 50% hypertonic		+	+	+
Glucose with sodium chloride	Injectable solution, 4% glucose + 0.18% sodium chloride		+	+	+
Potassium chloride	11.2% solution in 20ml apoule			+	+
Sodium chloride	Injectable solution, 0.9% isotonic		+	+	+
Sodium hydrogen carbonate	Injectable solution, 1.4% isotonic		+	+	+
Compound solution of sodium lactate	Injectable solution			+	+
Water for injection	2ml, 5ml, 10ml ampoules		+	+	+
26.	**Vitamins and minerals**				
Ergocalciferol	Capsule or tablet 1.25mg (50000 IU)				+
	Oral solution 250mcg (10000 IU/ml)				+
Pyridoxine	Tablet 25mg (hydrochloride)		+	+	+
Retinol	Sugar-coated tablet 10000 IU (as palmitate) (5.5mg)		+	+	+
	Capsule 200000 IU (as palmitate)	+	+	+	+
	Oral oily solution 100000 IU/ml in multidose dispenser (as palmitate)	+	+	+	+
	Water miscible injection 100000 IU (as palmitate) in 2ml ampoule		+	+	+
Riboflavin	Tablet 5mg.		+	+	+

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Therapeutic Category and Drug	Dosage Form and Strength	Usage Level			
		V	P	S	T
Thiamine	Tablet 50mg (hydrochloride)		+	+	+
Vitamin B Compound	Tablet, Thiamine 5mg (hydrochloride) + Riboflavine 2mg + Nicotinamide 20mg + Pyridoxine 2mg (hydrochloride)	+	+	+	+
Calcium gluconate	Injection 100mg/ml in 10ml ampoule			+	+
Calcium carbonate	Tablet 625mg (equivalent to elemental calcium 250mg)	+	+	+	+

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Part II

Selected Monographs

Right to Essential Drugs at Affordable Price for Better Health — a Consensus Approach

Dr. Naresh Banerjee*

1. Introduction

1.1 **Health** has been defined by the World Health Organisation as a state of complete physical, mental and social well-being and not merely absence of disease or infirmity. Right to health is a basic fundamental right and merits inclusion in the Fundamental Rights Chapter of the Constitution of India instead of its present placement under the non-obligatory Directive Principle Section.

1.2 Government of India, a signatory to the Alma Ata Declaration, has committed in its Health Policy Document of 1993, to adopt "Health for All by 2000 AD".

This implies that the Government of India should adopt adequate measures so that all the people of our country enjoy a good level of health that would permit them to lead a socially and economically productive life.

1.3 To maintain 'health', we need adequate food and water supply, proper housing with good sanitation facilities including proper disposal of wastes, and basic health education. Besides, adequate measures against preventable diseases, including access to immunisation facilities and also measures against environmental pollution must exist. Finally, supply of 'essential drugs' of good quality, in adequate quantity, and at affordable price to all the people must be ensured. Right to essential drugs can justifiably be considered as an integral part of right to health.

2. Socio-economic, Health and Drug Situation in India

2.1 With a population burden of over 91 crores (that ammounts to 16.5% of the gobal population) in 1994-95 that appears to cover only 2.6% of the global land area, India accounts for 22% of the global illness (morbidity).

In India 74% of the people live in villages and 50% of the people are below poverty line. Nearly 60% of the children born are underweight. Every year 16.5 millions of children are born, 1.6 millions children die annually within a year of their birth mainly due to lack of adequate preventive measures, nutrition and sanitation. Infant mortality rate is as high as 90 per 1000 live births, only 45% of the people have access to potable water, and about 25% to 30% to modern treatment facilities, that too, partially.

2.2 Incidence of various types illness are on the rise; such as malaria, tuberculosis, kalaazar, infective hepatitis, diabetes, pulmonary emphysema, cardiac diseases, leprosy, cancer, leukaemia, thalassemia, arsenic poisoning and allergic skin diseases, AIDS, jaundice, kidney disease. Emergence of large numbers of drug-induced diseases due to irrational prescribing habits and over-the-counter sales due to unethical dispensing habits and marketing practices, is also causing concerns (Table I).

*Chairman, Organising Committee, International Seminar on Rational Use of Drugs, April 22-24, 1995, at Siliguri, India.

Table I : Health Picture of West Bengal, India, Developing and Developed Countries.

	West Bengal	India	Developing Countries	Developed Countries	World Average
1. Birth rate	28.1	30.2	28.1	14.6	25.0
2. Death rate	8.4	9.7	9.3	9.5	9.3
3. Infant mortality rate	63.0	80.0	70.0	12.0	63.0
4. Expectation of life at birth (years)	62.0	61.2	60.8	74.8	62.6

2.3.1 There are above 8500 drug manufacturing units in India, out of which about 8000 are small scale units, about 350 units are medium, 17 public sector units (both Central & State Govts) and the rest are big national and multinational units. In 1994-95 about Rs. 7,500 crores (approximate) worth of drugs were manufactured in India including bulk drugs and formulations, which accounts for 2.8% of the drug production.

2.3.2 In 1979-80, it was assessed by the Govt. of India that by 2000 A.D. our country will need about Rs. 16,000 crores worth of rational and essential drugs. Taking into account the price hike, inflation, deficit fiancing, new industrial policy, the requirement of rational drugs will worth about Rs. 40,000 crores by 2000 A.D.

2.3.3 There are about 70,000 drug formulations in the Indian market. More than half of these are irrational or hazardous and profit-oriented marginal remedies, with hundreds of brand names for a single generic products. Hardly 30% of these formulations are therapeutically rational.

2.3.4 The Govt. of India in keeping with the dictates of the I.M.F. and World Bank adopted New Economic and Industrial Policy, accepted the GATT and Dankel Agreement with its octopus - like tentacles as innuciated in TRIPS, TRIMS and GATT, signed to join World Trade Organisation with effect from 1st January 1995.

2.3.5 The Govt. of India has devalued its currency, grossly modified the Drug Policy of 1986 on 15th Sept, 94 on following issues:

(a) Reduced the span of price control to drugs only, which was 142 in 1986 DPCO, 347 in 1979 DPCO.

(b) Raised the MAPE (maximum allowable production expenses) uniformaly to 100%.

(c) Fera equity diluted from 40% or more without screening the Fera Companies should be considered at par with the Indian companies. The Indian companies shall have to survive by competing with the foreign multinational companies having global marketing base, production units in various countries along with extensive research facilities.

(d) Reduced the number of drugs reserved for public sector, to make them more sick.

(e) Automatic approval of foreign technology without screening is going to hamper indigenous technology.

(f) Unrestricted import facilities

will convert our country into a dumping ground for obsolete drugs which may have been discarded in the country or origin.

2.3.6 Govt. of India has grossly amended the Indian Patent Act 1970 on 1st January 1995 which is going to affect the development of Drug Industry paticularly small, public and medium sector units, and also indigenous technological self-sufficiency adversely. The big national sector will try to survive as the junior partners of the multinationals. In this connection it has to be noted that the USA has not ammended its section 302, super 301 and special 301 for restricting imports and has not liberalised imports like the Govt. of India. Further, seven countries of Europe have also refused to ammend their constitution.

3. Steps Suggested for Adoption of Rational Drug Policy & Rational Use of Drugs

i) Drugs, pharmaceuticals and appliances should be the under the Ministry of Health & Family Welfare and shall have to be shifted from the Ministry of Chemicals, Petrochemicals and Fertilisers.

(ii) The drug needs should be assessed — preventive, curative and restorative, in keeping with the morbidity patterns, accidents, injuries, natural calamities, mass migration of population etc.

(iii) (a) To identify the graded lists of Essential Drugs for : i) Subsidiary Centres, ii) Primary Health Centers, iii) Block Health Centres, iv) Rural and Urban General Hospital and Subdivisional Hospitals, v) District Hospitals, vi) Medical College Hospitals, vii) Speciality and Superspeciality Disciplines.

(b) The list of Essential Drugs as per WHO technical report series no 825 published in 1992, contains about 260 drugs in 27 groups and several sub-groups in each of the group with which more than 90% cases could be treated effectively. Production of these drugs through good manufacturing practice should get due priority.

iv) Steps should taken to ensure supply of enlisted drugs in adequate quantity of good quality, manufactured through good manufacturing practice, in generic names, at affordable price with free supply of the indegent.

v) Drug control and testing laboratories should be updated and extended with provisions for deterent punishment for manufacturers of substandard and spurious drugs, plugging the legal loopholes. The drug control dept. should be adequately staffed with clinically - oriented technical experts.

vi) To ensure ethical promotional habits for the drug manufacturer, drugs should be marketed in generic names. This would avoid confusions that prevail with hundred of brand names for single generic drug. Crores of rupees are spent by the manufacturer to create and build brand image which is included in the price structures of the drugs. Pharmaceuticals houses should provide unbiased information about efficacy, adverse reaction, dosage form, time of intake through folders or leaflets in local and regional languages.

vii) The packages should contain manufacturing batch no, with dates

of manufacture and expiry date, storage temperature, light sensitivity, with banning of over-the-counter sale.

4. To Set up National Drug Authority (NDA) of India

i) For impelemnting Rational Drug Policy and Rational Use of Drugs it is essential to set up a National Drug Authority of India as has been suggested in the item No. 16 of Modification in Drug Policy 1986. Ironically, this was originally suggested by the Hathi Committee in 1976.

ii) NDA should be set up through a special Act of Parliament with the Dept. Health and Family Welfare as the highest Apex Body to deal with all the aspects and affairs concerning drugs and pharmaceuticals. It should be a statutray body to be constituted with representative from Parliament Members, representatives from Medical Profession, Pharmaceutical Profession, Medical Council of India, Pharmacy Council of India, representative from Pharmaceutical Manufacturing Industry and Pharmaceutical Workers and Applied and Clinical Pharmacology Professors, ICMR, CSIR, CDRL, Institute of Bio-technology, Drug Controller of India along with Drug Controllers of a 6 major States. Director of Central Drugs Laboratory, Director of Indian Institute of Chemical Biology, Director General of Health Services, representatives from Legal Professon, representatives of Drug Testing Loboratories, Representatives from Voluntary Health Organisations, technical representatives from other ministries concerned (not non-technical bureaucrats), representatives of scientific organisations working in the field. All these representatives will constitute the Council of NDA.

iii) The NDA Council should set up several Subcommittees for specific jobs such as: i) Monitoring and enfircing production controls; ii) Monitoring and enforcing price control; iii) Drugs and Consmetic Act Ammendment Sub-committee; iv) Drug Quality Control and Drug Testing Committee; v) Technical Sub-committee to weed out irrational drug formulations drastically and to incorporate effective new drugs; vi) publication of quarterly prescriber's journal; viii) publication of quarterly jounal for the pharmacists; viii) to set up ethical for product publicity; iv) to steamline the Drug control dept. and Drug Testing Laboratoriesl x) to set up Adverse Drug Reaction Centres in various zones of India attached to the hospitals with prescription monitoring; xi) to organise refresher courses and ongoing education for the doctors and pharmacists at regular intervals along with education for the consumers.

The suggestions referred above if implemented will go a long to achieve implementation of Rational Drug Policy and Rational Use of Drugs. United movement of all sections concerned are very vital to ensure optimum health care for our people.

Rational Drug Use and National Drug Policy

M. Heilling Borda*

The rational use of drugs demands not only that the appropriate drug be prescribed, but that it be available when needed, and at a price people can afford; that it be taken in the right dose, at the right intervals and for the right length of time; and that it be effective, of acceptable quality and safe.

Few, if any, would disagree with such a definition, so does this mean that we prescribe, dispense and take medicines in a rational way? On the contrary, most studies demonstrate that while we may agree in the abstract on what is rational we don't act on that agreement in practice. So what is the reality behind the rhetoric?

Perhaps our greatest irrationality is in using drugs when these are not needed. It is well known that many clinical symptoms are caused by self-limiting sickness which will pass without treatment, or even despite it. In some clinical settings as few as half of all patients may benefit from a drug regimen, but many more will be given a prescription. The false perception that a pill exists for every ill is thus enhanced.

Even when drug is needed, polypharmacy is now so common that patients come to expect 4 or 5 different drugs on each prescription. And in some countries where drug shortages occur or distribution is uneven, it may mean that while one patient gets too many drugs other in need are deprived of any at all. Not that the behaviour of the patient/consumer appears much more rational. Compliance, i.e. taking medicine as prescribed, seems at best to be around 50% and in many cases as low as 20%, and it appears probably that poor communication between prescriber and patient may be in a large measure responsible.

Irrational use frequently takes another form. When the patient cannot afford the full treatment, the pharmacist, will dispense a dose for a day or two, or possibly - if the patient looks sufficiently prosperous - advise an unnecessarily expensive medication. And in many market places, shops and bazaars, pills, capsules, injections etc. are sold by the piece, like other commodity, in the hope that "modern" medicine will do the trick.

Who is responsible? And what, if anything, can be done? The simple answer is that all have a role to play in rational drug use: governments; industry; health workers; educators; consumers. To play a responsible role we need objective and complete pharmaceutical information; we need the data and skills to match medicine with morbidity, and to estimate the quantities required; we need to move from the theoretical to the practical in our education of prescribers and dispensers; and we need to instruct our children and fellow citizens in how to take medicines and how they interact with the body. We also need to recognize that poor communication between prescribers and recipients is a serious problem in developing and developed country alike, and that knowledge which cannot be shared is like a torch with a dead battery giving light to none.

Fortunately, the powerful light of wordwide debate is currently contributing insight into our use of drugs. Groups representing many interests are coming together in constructive discussion and analysis of

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the problems. There is growing awareness that to ensure an adequate supply of safe and effective drugs of good quality at an affordable price, which are properly used, every country should have a national drug policy as an intergral part of its health policy.

The ministry of health is the most appropriate department to take the lead in developing a national drug policy. However, other government departments and agencies will need to participate in its development, since its success will depend on the interest and wholehearted endorsement of government officials at the highest levels. Endorsement by sectors such as planning, finance, education, legislation, industry and commerce, are of particular importance, since decisions regarding registration, import quotas, foreign exchange allocations, tariffs, marketing, and human resources development may all have significant effects on drug procurement, manufacture, distribution and use.

A policy is a guide to action and a commitment to a goal. A primary goal will be to make essential drug available to the entire population, and to assure the safety, efficacy and quality medicines provided to the public. The regular availability of drugs at health facilities increases attendance by increasing the credibility and acceptance of health workers, and facilitates their important role in preventive medicine. Other health related goals include improving prescribing and dispensing practice, and promoting correct use of medicines by the public.

A national drug policy also has economic goals of which the principal will be to lower the cost of drugs to the government and the public, and to reduce the foreign exchange drain from drug imports through wiser purchasing. It will need to consider the interrelationship between the public and private sectors since drugs may be prescribed in the public sector but purchased in the private sector. It will also need to consider the fact that self-medication accounts for a high proportion of the drugs consumed in many countries. And finally, the policy will include national development goals, such as an improved infrastructure, increasing human resource skills in management, pharmacy and medicine, or promoting the local production of drugs.

Increasingly, countries are taking up the challenge to develop comprehensive national drug policies and in doing so, calling on the participation of the many sectors involved in this complex area. Questions which governments will need to ask include: What is the present situation? What are our needs, immediate and future? Which are our priority objectives? Where will the work be done and who will do it? How long will it take? Whom can we learn from? How much will it cost? Is external support needed? Who will monitor progress ?

The cornerstone to a national drug policy will be legislation to ensure the safety, responsible marketing, rational selection and use of drugs entering the national market, with adequate enforcement measures to ensure that resources spent on modern pharmaceuticals are not wasted but make a positive contribution to the health of the population. Legislation should be accompanied by a plan of action for implementation. This may have to be phased, since it will not always be possible to implement all components simultaneously.

The exercise of formulating a natuional drug policy provides a unique opportunity to evaluate the present, to identify problems and to plan a strategy for the future involving all actors in the pharmaceutical and health field.

Essential Drugs and National Drug Policy for India

Dr. K. Balasubramaniam*

Health is a fundamental human right. The Constitution of India directs the State to regard the improvement of public health as one of its primary duties. The State is, therefore, committed to the promotion and preservation of the health of every Indian. This will require among other things, efficient health care delivery and pharmaceutical services based on rational health and pharmaceutical policies.

Health care delivery and pharmaceutical services, even in their most elementary forms, remain inadequate in many developing countries like India. There are several constraints facing these countries in providing optimum health care to the whole population. Finding solutions to these constraints have been a recurrent leading agenda item in the meetings of the World Health Assembly (WHA). The World Health Organization (WHO) and the United National Children's Fund (UNICEF) organised an International Conference in Alma Ata, Soviet Union in September 1978 to explore ways and means of providing optimum health care for all. Primary Health Care (PHC) was identified as the key to provision of Health for All.

Mr. JP Yadav the Indian representative to the Alma Ata conference in supporting the concept of PHC told the participants, among other things, the following :

> "..It is important that health care should not mean provision of all the sophisticated health facilities to a few and denial of even the basic essentials to many..
>
> The health scene in most of the countries of Asia and Africa suffers from severe distortions. It is painful to say so but this is the truth, the harsh truth. The city gets the best, the village the least.In India over the years we have built magnificent hospitals. All of them are in the cities..But we are now laying greater emphasis on primary health care in rural areas- on narrowing the gap between the village and the city, between the health 'haves' and 'have-nots'. The new direction which we have given to our health programmes seeks to take basic health care to the doorstep of the people in the villages!"

These admirable sentiments and noble ideas were the solemn promises made by the official Indian Government representative to the World Community in 1978 — promises that would transform the lives of the vast sections of suffering and poor Indian children, women and men. The promise was that the Indian Government would give a new direction to the health care services; formulate and implement a national health policy based on PHC as outlined in Alma Ata in 1978.

Primary health care has eight components, one of which is provision of essential drugs which is the topic of the present Seminar. How can a government with limited resources manage to provide essential drugs to all its people? The Director General of WHO has the answer to this problem. Addressing the World Health Assembly in Geneva in April 1992, he stated. "National drug policies and essential drug

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programmes are now and in the foreseeable future, the best means we have to make available of pursuing and eventually attaining the dual objectives of rational management of drug resources and better health for all."

Drug Policies in India

Historically, India with its ancient civilization, has been a pioneer in contributing several original concepts, thoughts and ideas that have enriched mankind. This has been true of drug policy making too.

It was India that for the first time, before WHO published its first selection of essential drugs, introduced the concept of an integrated rational drug policy based on the 'concepts of essential drugs and their rational use'. In 1974, the Government of India set up an expert committee, popularly known as the Hathi Committee, to assess the existing pharmaceutical supply system and recommend remedial measures. The Hathi Committee submitted its report in 1975. The Committee provided critical analysis of the empirical data it collected on the existing pharmaceutical supply system in India. Based on its analysis the Committee recommended a comprehensive, integrated rational drug policy in keeping with the concepts of a limited number of essential drugs. The report was published in 1978.

The Government of India announced a National Drug Policy in March 1978. But according to researchers in the Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), the Hathi Committee's major recommendations were either rejected or diluted. This policy was replaced in December 1986 by a new drug policy. It was called "Measures for Rationalization, Quality Control and Growth of Drugs and Pharmaceutical Industry in India", and was developed by the Department of Chemicals and Petrochemicals, Ministry of Industry. The major objective was industrial expansion. It was described by the people of India as an "anti-people" and "pro-industry" policy.

The new policy announced in December 1986 was followed by a Drugs Price Control Order (DPCO) issued in August 1987 replacing the DPCO on 1979.

Researchers from JIPMER who had studied the new drug policy had the following comments :

> "In January 1987, under the Chairmanship of Dr. Y. K. Alagh a committee was constituted for rationalisation, quality control and growth of drugs and pharmaceutical industries. Very soon Dr. Alagh was discontinued and a new committee reconstituted under Dr. V. Kelkar in March 1987. Yet another member Prof. V. Ramalingsamy was discontinued some time later.
>
> The basic objective of the Kelkar Committee was to identify the drugs to be included in category II for the purposes of price control. But the most interesting aspect was that while selecting category II drugs for price control purposes, the list of category I drugs was not available to the Committee.
>
> Category I drugs were meant for National Health Programmes while category II were claimed to be essential drugs for the health care needs of the Community.
>
> The approved national health programmes cover eleven areas. However, the DPCO recognised only six areas for the purpose of price control. Drugs and vaccines for the expanded programme of immunisation, goitre control, sexually transmitted diseases control, family planning and guinea worm eradication programmes have been excluded from the list of category I bulk drugs for price control. The national

programme for control of blindness had nine drugs but Vitamin A was not included.

The Kelkar Committee identified 154 drugs and proposed them as essential drugs. The Government of India accepted 139 as essential drugs for price control purposes. The entire list of drugs appears to have been selected more from a commercial point of view to help the drug industry and not from a health point of view of promoting the health and wellbeing of the people." - *The National Drug Policy: S.C. Pradhan, et al. The Eastern Pharmacist, November 1989, pp. 17-20.*

The Government of India has now come with yet another drug policy in September 1994 called "Modification in Drug Policy". Critical examination of the modifications indicate that these will not meet the needs of the country and the people, namely, making available essential drugs at affordable prices to all those who need drugs; more problems will arise and changes will have to be made again but vast sections of the population will continue to suffer due to non-availability of essential drugs.

The evolution of drug policies in India since 1978 clearly demonstrates that India offers a classic example of adhoc policy making. Policies are formulated and implemented, piecemeal problems arise and the Government is forced to change course at midstream. Modifications are incorporooted to the existing policy and further new components are added and the same cycle repeats again and again. Every time the existing policy was revised, the number of essential drugs under price control was reduced.

The World Health Organization had analysed the achievements of the Indian national drug policies in The World Drug Situation, WHO, Geneva, 1988. Among other things, it was stated, "Inspite of the phenomenal growth of the drug industry, only 5-6 percent of the population was able to afford or to procure the essential drugs they needed. With the government decontrolling more and more essential and life-saving drugs, the prices of these drugs will increase and the problems are likely to be accentuated..India provides a paradoxical example of overproduction of non-essential drugs existing parallel with shortage of essential drugs for the major diseases affecting the people. In the Indian drug policy economic priorities have taken precedence over health priorities."

The way that the pharmaceutical industry in India was allowed to develop and grow has resulted in structural injustice. As such the pharmaceutical situation is both tragic and scandalous. Victims of disease have also become victims of neglect by government and victims of exploitation by those hungry for profits.

More than ever, India needs a new paradigm about the way the health needs of the people are viewed. A new framework is esential to ensure: (1) the availability of essential drugs at prices the people can afford and (2) the rational use of these essential drugs. Among other things, structural changes and long-term planning are necessary. Among the structural changes India needs, one key element is essential — a health oriented rational drug policy based on the concepts of essential drugs. Such a drug policy should be based on five cardinal principles: Need, Effectiveness, Safety, Economy and Access.

Rational Drug Therapy in Children

Dr. Uday Bodhankar*

Prayer for a pediatrician, in practice or in academics : *Practice and Promote Rationalisation in Choosing a Drug and its Administration.*

- Select the drugs carefully and use them with reason. Any medicine basically is potentially a poison.
- Doses should not be empirical. Give the drugs as per needs in milligrams per kilogram or surface area of the kid.
- Underdosing is ineffective and results in drug resistance. Overdose may be very toxic and may end baby's existence.
- Pricks in the buttocks or in the arm should be avoided. Use lateral side of the thigh and give the injections carefully.
- Sterilise instruments properly; use of autoclave is desirable; mere boiling may be ineffective; disposable gadgets are preferable.
- Precision and care is necessary. We are bound by duty and ethics for using rational drug therapy.

"From inability to let well alone, from too much zeal for the new and contempt for what is old; from making cure of the disease more grievous than endurance of the same, good Lord deliver us" — Sir Robert Hutchinson.

How true these words are ! One often sees children suffering more from the treatment prescribed rather than the disease itself. *Rational drug therapy* with appropriate chemotherapeutic agents for management of common childhood diseases is most crucial to enhanced child survival.

Guidelines for rational drug therapy

It is desirable to select the most specific and appropriate therapeutic agent after having established the diagnosis of underlying disease process. The drug should be administered through the recommended route, given in an optimal dosage schedule and for the recommended duration of time. A large number of diseases are self-limiting and unnecessary medications should be avoided, It should be remembered that no drug is entirely safe, The physician must use drugs with which he is familiar regarding its efficacy, safety and side effects. It is recommended to prescribe the minimum number of appropriate and inexpensive drugs and thus to avoid polypharmacy. Polypharmacy reflects lack of confidence on the part of the physician.

Antibiotics and corticosterolds in fever

The antimicrobial agents should be used only when diagnosis of bacterial infection is established, their use merely as an antipyretic agent in every case of fever is dangerous.

The widespread practice of using corticosteroids as a panacea for all diseases and for producing rapid defervescence of fever is associated with undue risks and should be avoided.

Drug combinations

Several combinations of drugs available in the market are unscientific and they should not be used e.g. expectorant with a cough sedative, antibiotics or analgesics with steroids, streptomycin with pencillin, praracetamol with ibuprefen etc.

Drug dosages in Children

Children are not 'mini-adults' and the dose recommended for adults cannot be

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modified for use in children by any simple formula. Dosages in children should be calculated on the basis of body weight or surface area. A practitioner should always keep a ready reckoner in the form of a drug dosage chart on his table so that he can immediately refer to the same whenever required.

Misuse of injectables

In children the drugs should preferably be administered through oral route. The physician should not accede to the wishes of parents to give painful injections to children because of the mistaken belief that are more effective than oral medicines. It must be remembered that injections are associated with risks of abscess formation, anaphylaxis, transmission of viral disease (Hepatitis B and HIV) and augmentation of paralysis due to poliomyelitis. In ambulatory pediatric practice apart from use of vaccines, there are limited indications for using injectable medicines. Apart from vaccines, the general practitioner may stock injections of epinephrine, hydrocortisone and penicillin to manage life-threatening emergencies like bronchial asthma, anaphylactic reaction, meningococcemia and for rheumatic prophylaxis. Nalorphine and naloxone can be life-saving in children suspected to have poisoning and overdose due to opium, morphine, codeine, diphenoxylate hydrochloride and pentazocine.

When indicated, the intramuscular injection should be given over the upper part of lateral side of thigh instead of gluteal region to avoid possible damage to sckatic nerve.

Symptomatic Management

Fever is a protective response on the part of body to fight against infection and therefore, no attempt should be made to give antipyretic agents in children with low grade fever. However, there is a risk of occurrence of febrile convulsions in young children with high-grade fever. Administration of paracetamol 10-15 mg/kg/dose or ibuprofen 10mg/kg/dose are equally effective and safe. Acetylsalicylic acid should be avoided as an antipyretic agent due to the potential risk of development of Reye's syndrome. Ordinary tap water sponging on the body is often helpful. Avoid ice-cold water for sponging because it is uncomfortable and may cause shivering.

Unlike fever symptomatic therapy for vomiting should be avoided and all efforts should be made to identify the cause of vomiting. Metoclopramide hydrochloride (0.5 mg/kg/dose) and domperidone (0.2-0.4 mg/kg/dose) are comparatively safe antiemetic agents if used judiciously. Repeated doses of these drugs should be avoided. If vomiting persists even after 2 doses of antiemetic agent then the child should be evaluated by a specialist.

Abdominal colics are rather common in infants and young children. Administration of a carminative mixture or the concoction of 'saunf' and 'ajvain' may provide relief. Dicyclomine hydrochloride 5-10 mg/dose), and pipenzolate methyl bromide 2.5-5 mg/dose) are safe antispasmodic agents. Placing the child on abdomen and cautious application of local heat are useful to relieve abdominal colic.

Sedating children

Sedation may occasionally be required for relef of restlessness and irritability. But before giving sedation to restless/irritable child, the child should be carefully evaluated as these symptoms may reflect a serious underlying disorder like meningitis, hypoxia (due to pneumonia/bronchial asthma etc.) Sedation is contraindicated in children with pneumonia, bronchial asthma and head injury due to the risk of respiratory depression and its interference in the evaluation of level of conciousness. In infants with acute gastroenteritis, irritability and restlessness are important symptoms

of thirst and it should be managed by administration of ORS or home available fluids rather than sedatives or antispasmodic agents. Triclofos sodium (10-20 mg/kg/dose) and promethazine hydrochloride (0.5-2.0 mg/kg/d daily 3 doses) are safe and effective sedatives for use in children whenever necessary. They should be given orally rather than through an injection.

Frequent change of antibiotics

A trial of a minimum of 3 days is mandotory in most cases before the antibiotics are changed. During management of any infective disorder, when response to therapy is unsatisfactory, it will be appropriate to check the correctness of diagnosis, dosages and acceptance of the prescribed drugs rather than to go on changing the antibiotics blindly. If there is a localised collection of pus, all efforts must be made to identify the site of abscess. Unless it is drained, no amount or antibiotics are likely to dry it. Efforts should be made to identify an obstruction due to foreign body or congenital malformation in the lungs and uninary system in a non-responsive infection.

Parasitic infections

Apart from prescribing specific anthelmintic therapy, it is essential to give detailed advice and guidance to the family for treatment of all the family members and prevention of recurrence. The principles of personal hygiene like thorough hand washing before eating, keeping the nails trimmed and avoidance of orofecal contamination should be stressed. Children should be encouraged to use flush latrines for defection. The fresh fruits and vegetables should be eaten after peeling and thorough washing under running water. The frequency of deworming should not be less than 6 months.

Mebendazole (100 mg twice a day for 3 days) or albendazole (200 mg single dose for children below 2 years and 400 mg single dose for older children) or pyrantel pamoate (10 mg/kg single dose upto a maximum of 1.0 g.) may be given for round worms, hook worms, tape worms, Strongyloides stercoralis and mixed infestations.

For Enterobius vermicularis (thread worm) infestation. mebendozole (100 mg single dose) followed by a repeat dose two weeks later may be given to break the cycle due to autoinfection.

Metronidazole (10-15 mg/kg/d in 3 div doses) or tinidazole (10-15 mg/kg/d in 3 div doses) should be given for a period of 5 to 7 days for giardiasis.

Acute amoebic dysentery is treated by administration of combination of metronidozole (20-30 mg/kg/d in 3 div doses) or tetracycline (in older children) for a period of 7 to 10 days.

Acute diarrhoea

In a child with acute gastroenteritis, the emphasis should be placed on prevention of dehydration, correction of fluids and electrolyte disturbances and provision of nutritional needs of the child. The mother and physician must appreciate that irritability and excessive crying in these children is due to thirst rather than abodominal colic. The mother must be explained about the importance of ORS and given health education to prevent recurrence of diarrhoea.

Staravation must be avoided and mother should be advised to continue breast feeding or give other milk (if top-fed) and semi-solid foods especially, rice, khiichri, egg white and banana. The fluid losses through the stools should be replaced by the administration of commercially availlable ORS (WHO formula, moong dal, soup, rice water, coconut water etc.

Use of antibiotics in acute diarrhoea should be restricted to following situations:

i) Blood and mucus or leucocytes in the stools.

ii) Children with cholera.

iii) Infants less than 3 months of age and children with severe PEM and acute diarrhoea would require careful evaluation for use of antibiotics.

Co-trimoxazole or nalidixic acid is the drug of choice for bacillary dysentery. Tetracyline or furazolidone is indicated for children with cholera.

The use of antiemetic agents should be avoided as vomiting often settles following ORS therapy. The role of antispas-modics, binding agents and antisecretory agents is doubtful and they should be avoided.

Acute respiratory infections

Most cases of common cold are self-limiting and need management with symptomatic therapy and simple home remedies like administration of 'tulsi' tea, honey and humidity. Paracetamol or Ibuprofen may be administered for relief of pain , discomfort and fever. Cough mixtures containing antihistaminics are often unnecessary and may even make the child more uncomfortable by drying the nasal secretions and worsening nasal block. The use of medicated nose drops should be avaoided and instead local instillation of normal saline in the nostrils followed by local toilet with the help of cotton swab is recommended to relieve the nasal obstruction. There is no therapeutic utility of routine administration of antibiotics because common cold is caused by viruses. The antibiotics (erythromycin or amoxycillin) may be administered only if there is appearance of fever during the course of upper respiratory catarrh or if there is persistent purulent nasal discharge. One must try to identify cases of streptococcal pharyngitis and otitis media which need the antibiotic management. Presence of follicles in the throat and/or tender enlargement of tonsillar group of lymphnodes is indicative of streptococcal pharyngitis.

The drug of choice for streptococcal pharyngitis is penicillin which is administered in oral dose of 10 mg/kg/dose 4 times/d given in empty stomach for a period of 10 days. If a patient is allergic to penicillin, erythromycin (20-40 mg/kg/d in 3 div doses) or first-generation cephalosporin may be given.

Amoxycillin (50 mg/kg/d in 3 div doses) or co-trimoxazole (5 mg/kg/d of TMP in 2 div doses) should be administered for 7-10 days in cases of otitis media. There is no therapeutic utility of ear drops. Timely myringotomy should be undertaken if eardrum is found to be bulging to prevent perforation.

Lower respiratory infections

A significant number of actute lower respiratory tract infections are caused by viruses. But nevertheless most pneumonias are treated with antibiotics because it is not easy to differentiate between viral and bacterial pneumonia on the basis of clinical examination and routine investigations. Young infants (below the age of 3 months) with bronchopneumonia should be admitted to a hospital and managed like a case of neonatal septicemia.

Children between 3 month to 3 years of age with bronchopneumonia should be treated with ampicillin while children above 3 years of age can be safely managed with injectable penicillin or syrup amoxycillin 50 mg/kg/d in 3 divided doses.

Children with bronchopneumonia should be referred to a hospital for further management if respiratory rate is more than 60 per minute with substernal retractions or if the child has cyanosis, refusal of feeding. Lack of clinical improvement within 2-3 days of ambulatory therapy should make you seek specialist opinion.

Bronchial Asthma

Acute attack of bronchial asthma is

best treated by salbutamol (100 ug/dose) or terbutaline (250 ug/dose) with the help of metered dose gas-propelled inhalers or wall-mounted or compressed air aerosol inhalers. Metered-dose inhalers with beclomethasone alone or in combination with salbutamol are also available and can be used. The metered-dose inhalers must be used along with a spacer device to improve its efficacy. When aerosol therapy is not available, epinephrine (0.01 ml/kg of 1:1000 solution per dose) can be given subcutaneously and the dose can be repeated after 15-20 minutes while monitoring heart rate and blood pressure. In addition the child should be administered oral aminophylline or theophylline (15-20 mg/kg/d 3 div doses) along with salbutamol (0.01-0.1 mg/kg/dose in three doses per day). Administration of relatively low doses of medications is one of the common reasons for poor control of bronchial asthma. However, if a patient is receiving erythromycin concurrently the dose of aminophylline/ theophylline should be reduced by 25 per cent. In a severe or unresponsive attack of bronchial asthma, one should not hesitate to administer a short course of oral corticosteriod which can be tapered over a period of 5-7 days. There is no therapeutic utility of expectortant cough mixture. Use of antihistaminics is indeed contraindicated in a patient with an attack of bronchial asthma. Expectoration can be facilitated by ensuring adequate hydration of the patient and by giving steam inhalation.

Malaria

Most cases of malaria due to P. vivax are responsive to chlorqorine phosphate which is the drug of choice, It is given in the dose of 10 mg of base/ kg followed by 5mg/kg/6 hours later and same dose once daily for next 2 days. There is increasing incidence of resistance against most of the currently available antimalarials in P. falciparum cases. These patients can be treated with a combination of pyrimethamine and sulphadoxine (1.0 mg/kg of pyrimethamine and 20 mg/kg of sulphadoxine in a single dose) or a combination of pyrimethamine and sulphamethopyrazine in a single dose.

Urinary tract infections (UTI)

UTI are fairly common in children. The first attack of uncomplicated UTI is most commonly caused by E. coli. Two specimens of urine must be obtained for culture before initiating antibiotic therapy. The first line drug include amoxycillin/ ampicillin, co-trimoxizole, nitrofurantion or nalidixic acid given orally for 7 to 10 days. Urine culture should be repeated after one and six weeks of therapy. Urologic evaluation is recommended after first attack of UTI, for all male children and in female children with recurrent infections to identify predisposing factors, e.g., uretero-vesical reflux and renal scanning after six weeks of initial attack. Children with recurrent urinary tract infections should be referred to a hospital for proper evaluation and management.

Tuberculosis

For chemoprophylaxis in a child below 3 years of age without BCG vaccination, with recent conversion of Mantoux test and without any clinical or radiological evidence of disease, give INH (5 mg/kg/d single dose) and rifampicin (10 mg/kg/d single dose) for a period of six months. Children with primary pulmonory complex, tubercular lymphadenitis and progressive pulmonary tuberculosis are treated with a combination of pyrazinamide (10-35mg/kg/d single dose for 8 weeks only), INH (5 mg/kg/ a single dose) and rifamplicn (10 mg/kg/d single dose in emplty stomach) for 6 months.

Children with disseminated tuberculosis such as miliary tuberculosis, tubeirculoous meningitis, oste-articular and genitourinary tuberculosis are treated with

a combination of 4 drugs i.e. streptomycin, pyrazinamide, INH and rifampicin, continued for a period of at least 9 months to one year. There is no need to given pyridoxine along with INH in children except when they are seriously mailnourished.

Febrile convulsions

In a child with an attack of typical febrile convulsion, efforts should be made to bring down the temperature by administration of an antipyretic and hydrotherapy. Intravenous diazepam can be administered in order to control convulsions. To prevent recurrence of a subsequent attack of febrile convulsions, the mother should be advised to give antipyretic at the onset of fever. Long term phenobarbital therapy is indicated in children with frequent attacks (more than 4 attacks per year) of febrile seizures of children with associated developmental retardation.

Children with recurrent seizures or developmental retardation should be referred to a specialist for necessary work-up and management.

Poisoning

The general practitioner should be able to provide first-aid to children with common accidental poisonings. The child should be encouraged to drink water or milk to dilute the poison in the stomach. Syrup of ipecac (1.0 ml/kg) orally followed by a cup of water should be administered to induce vomiting. Its use, however, is contraindicated in infants below six months, children who are having seizures or comatosed and in children who are victims of kerosene and caustic poisoning. If syrup of ipecac is not available, a careful gastric lavage should be undertaken with normal saline to remove the poison. Gastric lavage, however, is contraindicated in children who have ingested kerosene or a caustic substance. Universal antidote such as activated charcoal (1-2 g/kg suspended in 4 parts of water) may be administered. Irrespective of the condition of the child, all patients of accidental poisoning must be referred to a hospital and no chance should be taken in such cases because condition of the child may worsen at any stage.

Vitamins and minerals

Tonics and vitamin preparations are useless as growth promoting agents. They are often used as appetisers in children who have food-fussyness but these agents are not expected to provide any benefit. Apart from lack of their therapeutic utility, some vitamins especially fat soluble vitamins (Vitamin 'A' and 'D') may actually be harmful in excessive doses. It is more desirable to spend extra time explaining the mother about importantce of balanced diet for promoting optimal growth and development of children. The trace nutrients should preferably be procured from the natural food source. Nevertheless, use of vitamins and minerals are indicated in the following clinical situations.

- Treatment of specific deficiency diseases such as iron deficiency anemia, megaloblastic anemia, xerophthamia, rickets, scurvy, beri-beri, pellagra etc.
- Children receiving prolonged broad spectrum antibiotics and anticonvulsant therapy.
- Children with malabsorption syndrome and cholestatic hepatitis should receive large doses of water soluble preparation of A, D, E, K vitamins.
- Children convalescing from prolonged illness.

To sum up and re-emphasise, it must be remembered that the rational drug therapy can be life-saving while unnecessary medications are not only useless but actually harmful. Every contact with the patient must be utilized to give health and nutrition education, health-promotive and

preventive advice regarding family planning, adequate spacing between children, Immunizations and prevention of accidents etc. One must always remember that no drug is entirely safe and this fact has been most wittingly overstated in a chinese proverb : *"If the whole materia medica is sunk in the sea, it is good for the mankind but bad for the fishes".*

Children and Drugs : Starting the Habit of a Lifetime

Andrew Chetley*

Children account for about one third of the world's population (UNICEF, 1993). Children have frequent but not usually serious illnesses. These illnesses are part of a natural process which develops their immature immune systems and helps to build immunity against common diseases.

Do children need to take a wide range of drugs for these illnesses ? On balance, no.However, in general, "too many drugs are given to babies and children" (Parish, 1989, p35). "Most childhood infections are caused by viruses and are self-limiting, that is, the child gets better without any treatment" (Barry and Hall, 1990). According to the World Health Organisation (WHO), two-thirds of all drugs used by children may have little or no value (Rylance, 1987, p11). Some of the more common examples of drug misuse in children are given in Table 1.

Table 1 : Some common examples of drug misuse in children

- Antibacterials for viral upper respiratory infections
- Decongestants for colds, resulting in unacceptable adverse efects
- Drugs to treat diarrhoea
- Oral anti-emetics for vomiting
- Antipyretic agents for fever
- Tricyclic antidepressants for bed-wetting
- Sedatives for sleepless children or those labelled hyperactive
- Spasmolytics for abdominal pain
- Appetite stimulants

Source: Rylance, G. (ed.), 1987. Drugs for children, Copenhagen : WHO, p 11

There are dangers to inappropriate drug use. More than 12% of in-patients between 1983 and 1986 at the Hospital Infantil de Mexico experienced adverse effects to the medication they had received before hospitalisation (Phillips et al, 1989). In the USA, a 1988 study found that 2% of 6, 546 paediatric admissions to hospital wards were due rto adverse drug reactions (Steele and Kearns, 1989).

One reason for the adverse reactions is that "children are not simply small adults" (Geukroger, 1991). Their bodies deal with drugs differently from adults. For example, the rate of metabolism is reduced; particularly in infants, the blood-brain barrier is more permeable and the kidney and liver are still developing,so the rate of elimination of drugs is reduced (Laurence and Bennett, 1987, p140). As a result, infants and children need lower dosages of drugs than adults. The calculation of appropriate dosage usually takes account of both age and weight (Henry 1991, p20).

The way children respond to a particular drug can be determined only through research and experience. However, most

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drugs do not have established doses for infants and children (AMA, 1986, p23). About three-quarters of the drugs on the market in the USA are either contraindicated or contain strong precautions for use in children, and nine out of every 10 contain warnings against use by infants and toddlers (Anon. 1990)

Antibiotics

Antibiotics are among the most frequently prescribed drugs for children. In the USA in 1986, about 35% of the 57.8 million prescriptions for children under the age of three were for antibiotics (Levy, 1990). However, they are often used inappropriately (Parish 1989, p35). They are not useful against viral infections. As viruses cause most childhood diarrhoea and respiratory illness — the two most common childhood illnesses — the use of antibiotics for these conditions is generally unnecessary.

WHO (1990) says that "antibiotics should be used only for dysentery and suspected cholera. In diarhoea of any other etiology antibiotics are of no practical value and should not be given."

The American Medical Association (AMA, 1986) advises that "routine administration of antimicrobial agents to patients with colds has been shown to be completely useless."

An International Consultation on the Control of Acute Respiratory Infections in 1991 concluded that "most children with cough do not need an antibiotic" (AHRTAG, 1992).

In practice, antibiotics are widely used for these conditions. In Brazil, for example, a survey of pharmacies found that pharmacy assistants routinely recommended antibiotics for young children with acute respiratory infections (Misago and Fonsea, 1991). A survey of pharmacies in Kenya found high levels of antidiarrhoeals containing antibiotics being used indiscriminately (Yudkin, 1990).

Antidiarrhoeals and cough and cold remedies

Children are also often targeted as suitable candidates for other products — especially over-the-counter remedies — to treat these self-limiting conditions. Promoting these types of drugs for children serves also a longer-term purpose in helping to create a profitable market for medicines in the next generation. Children who grow up with the habit of taking unnecessary medicine to relieve self-limiting illnesses are likely to spend a good deal on drugs within their lifetime (Jackson and Soothill, 1989, p32).

At least US $1 billion is wasted every year on inappropriate antidiarrhoeal drugs and cough and cold remedies for children. According to WHO, many of these preparations are useless and some are potentially dangerous (Anon, 1991).

Four million children a year die from diarrhoeal diseases (WHO, 1990, p1). Oral rehydration therapy plus continued feeding can prevent at least half of those deaths, at a cost of little more than 50 cents a child (UNICEF, 1990, p12).

"Antidiarrhoeal agents are ineffective and can prolong the diarrhoea. The disease is self-limiting and the real therapeutic goal is simply: adequate fluid intake. Drugs such as loperamide and diphenoxylate must not be used in children under 12 years of age" (Mellis, 1990).

Many cold medicines for children include an antihistamine which can have sedative effect. They are advertised with a picture of a child sleeping peacefully while relieved parent, usually the mother, looks on. The overt meassage is that the mother has livingly relieved her child's suffering;

the hidden message is that the mother can have some peace and quiet by giving her child this type of medicine. Because the antihistamines are often long-acting, their effects can continue for most of the following day, causing the child to have difficulty with muscle control, coordination and balance. Another ingredient included in many popular cold remedies, the decongestant pseudoephedrine, can cause sleep disturbances and nightmares particularly among young children (Grant, 1992,p46).

A recent report by Health Action International (Chetley, 1993) found that a high proportion of antidiarrhoeals, cough and cold remedies, analgesics and vitamin preparations — all products frequently used by children — contained ineffective or harmful ingredients (see Table 2).

Table 2 : Irrational, ineffective and harmful products (1990-1991)

Category	Region	Total number of products	Number and percentage with ingredients that are ineffective	hazardous	Irrational
Antidiarrhoeals	ME, A,C	52	36 (69%)	13 (25%)	n.a.
Cough and Cold	ME, A,C,P	448	384 (87%)	26 (59%)	157 35%
Analgesics	ME,A,C,P	508	10 (2%)	102 (20%)	169 33%
Vitamin Preparations	ME,A,C,P	636	378 (59%)	n.a	356 56%

Regions : ME = Middle East, A= Africa C=Caribbean, P = Pakistan; n.a. = data not available

Appetite stimulants, vitamins and brain tonics

Parents' fear of their children suffering from undernutrition or concern about the common childhood symptom of loss of appetite allows considerable scope for pharmaceutical companies to promote a range of unhelpful products. A particularly disturbing example is the promotion of drugs to stimulate children's appetite. As WHo has pointed out (Rylance, 1987, p48) :

"There is no evidence that the drugs and mixtures that are proposed as appetite stimulants have any effect on appetite. Therefore, these preparations should not be used."

In Brazil, a 1992 study of some 6,000 children aged 3 to 4 years found that nearly 60% had used one or more drugs during the previous two-week period and nearly 10% or the children had been given medicine daily for a month or more. Loss of appetite was the main reason for the use of medicines. The most common drugs used were combinations of vitamins and minerals (36.5%), appetite stimulants (11.3%) and iron (4.9%). Malnutrition was not associated with the use of these drugs. The Brazilian government tried to ban appetite stimulants in the early 1990s. but the pharmaceutical companies got the ban overruled in a court decision (Beria, 1993).

In November 1993, the US-based company, Merck, Sharp and Dohme (MSD) agreed to withdraw the indication of appetite stimulation from all formulations of its antihistamine, cyproheptadine, (usually sold under the brand name of Periactin). It also announced that it would withdraw all combinations of cyproheptadine and vitamins, the most popular of its products used as appetite stimulants. A key reason for withdrawal was a campaign by Health Action International which drew attention to the MSD's continued promotion of cyproheptadine as an appetite stimulant in Africa, despite its promise in 1986 to stop promotion.

Vitamins do have ligitimate but limited role in the therapeutics. Children who receive a balanced diet are unlikely suffer from vitamin deficiencies. Where deficiencies do occur, there is much more need to look at ways to improve the long - term intake of food, while sometimes providing a short-term supplement of one or two particular vitamins. The routine use of multivitamin preparations in children is simply a waste of money. In the UK, for example, vitamins can be prescribed to treat deficiency conditions under the National Health Service, but not as dietary supplements. All of the multivitamin preparations are rated as "less suitable" for prescribing (BMA and he Royal Pharmaceutical Society, 1992, pp 339-44)

However, children are an obvious target for vitamin manufacturers. In some cases, companies have gone to extraordinary lengths to ensure that children swallow their vitamin preparations.

In the Philippines in 1989, children were sent home from one primary school with a letter from the school doctor, a prescription for one bottle of the multivitamin preparation, Multi-Sanostol Syrup, made by Byk Gulden and a starter sample of the syrup (Anon, 1989).

Also in the Philippines in 1991, Bayer was promoting its multivitamin preparation in daily newspapers, with an invitation to children from 2 to 10 to write in to join its Kiddie Club.

In Malaysia, in January 1990, children at a kindergarten in Penang were given samples of Seven Seas multivitamin syrup. A representative of the company producing the vitamins returned to the kindergareen a few days later to sell the children large bottles of the syrup. The children also received an attractive toy as a free gift, with every bottle purchased, while the school received a monetary donation for allowing the promotion to take place (Zaini, 1990).

The Philippine letter also hinted that taking vitamins might improve a child's intelligence. Advertisements during 1989 for another multivitamin syrup Kiddi Pharmaton, went even further. The advertisements claimed the "body-building, appetite inducing" product produced by the Swiss Company. Pharmaton SA and distributed by Rhone- Poulenc could also contribute to "better concentration and even improve a child's IQ performance. During 1992, in the UK, three vitamin manufacturers were successfully prosecuted for claiming that their vitamin products could increase children's intelligence (Anon, 1992)

In Pakistan in 1991, the Spanish firm Ferrer, was promoting its vitamin B6 preparation for improved intellectual activity, as a treatment for "boredom and apathy" and to deal with "behavioural problems in difficult children".

Other substances are also promoted to improve children's performance at school. In Peru in 1991, the Belgian company, UCB, advertised its piracetam product, Nootropil, as something that would help children with "school difficulties" such as "memory problems, difficulty in learning lack of concentration, intellectual tiredness, poor performance, agitation and irritability" (Lopez Linares and Phang Romero, 1992,p8). There is no evidence that piracetam can perform any of the these miracles.

Long-term effects

These examples demonstrate some of the "considerable pressure" that parents and prescribers are under from drug companies to use their products. Far too often the result is the selection of "less than optimal or greater than necessary therapy" (Rylance, 1987,p6).

Dr. Mica Parda de Tavera (1988), the then Secretary of Social Welfare and Development in the Philippines, said in 1988 that she was disturbed to see her medical colleagues prescribing drugs for children that were often unsafe, ineffective or inessential.

"Drugs reinforce a curative orientation; yet most childhood health problems are easily prevented through immunisation programmes, proper nutrition, access to safe water and a clean environment and all the other inputs that boil down to one thing : economic development and upliftment... There is a role for drugs but it must be taken in context, used appropriately as needed and not through the creation of artificial demands."

WHO poins out that inappropriate use of drugs for children has both immediate and long-term consequences. For the present the waste of resources and the potential for unnecessary adverse reactions are both strong arguments to encourage more care in the prescribing of drugs for children. But the unknown psychological and social consequences for children of excessive and inappropriate drug use is a worry for the future as well. "Children may tend to grow up believing that drugs are the solution to many of life's problems" (Rylance, 1987,pp11-12)

Recommendations for action

1. Health workers should pause before prescribing any drug for a child and ask themselves whether the drug is really needed and, if it is, whether it is the least toxic, most effective and affordable therapy.

2. Similarly, parents should question health workers about the need for a drug for their children's illness. Before buying an over-the-counter preparation, they should consider whether it is really needed or whether an alternative non-drug solution exists.

3. Governments have a responsibility to ensure that health workers and parents have access to independent information about the correct use of drugs for children.

4. There should be no direct promotion of medicines to children. Governments should also strengthen controls on promotion of medicines aimed at paediatric conditions. They may wish to consider total bans on advertising medicines for children; or they may wish to look at ways in which promotion of medicines for children can be subject to additional restrictions to ensure that exploitation of parental fears is not used to sell drugs.

5. Governments should review the paediatric medicines on the market with a view to removing those that are hazardous or ineffective.

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Rationalism in Obstetrics and Gynecology

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The primary responsibility of a treating physician is to offer relief to the patient and the orther responsiblity is scientific commitment to rationalism. Both the factors are complimentary to each other and neither can be sacrificed. Though patient's relief can be guaged as specific and objective end point in therapy, optimum use of therapy within limits may be a debatable issue.

The classical role of the obstetric and gynecological specialist, treating individual patients and curing disorders remains very important in women's health care, but it is now considered as insufficient. He or she is expected now to be deeply concerned with the promotion of women's health at all levels. The obstetrician and gynecologist is unique from the standpoint of being both easily involved in legal entanglements because of his/her varied medical activities. In office/clinic, diagnosis counselling, drug dispensing, minor surgery and decision making take place, affecting not only the patient present, but often another one as yet unborn. In the labour and delivery room the physician monitors the well-being of these two patients, administers analgesics and anaesthetics, gives blood transfusions and performs operative maneuvers and procedures, quite unlike any other speciality. In the operating room the obstetrician - gynecologist assumes surgical risks equal to those of all other surgeons; Also, a higher at risk category pertains to the obstetrician-gynaecologist because of the far-reaching effects of these activities in the present, on a whole family unit, and in the future, on an individual with a projected life-span of 70 years[1]. Even today after nearly two decades, this statement by Hinshaw stands true, may be is more true. Further decisions taken by obstetrician-gynecologist affect many aspects of woman's life. The wide publicity given to all areas of this speciallity in many women's magazines, television, and other news media, compel the speciality physician to keep abreast. Though it would be impossible to device a complete list of Do's and Don'ts, it is imperative that the obstetrician-gynecologist remains physically and mentally alert, in this era, when the wide-spread faith that there should be a pill for every ill, a product of our scientific medical heritage, continues to exist.

Current Scenario: Some Glimpses

Obstetrics

Variations within areas as well as within hospitals in obstetric care including hospital admissions, lengths of treatment, operative procedures are well known and are not fully explained by population characteristics and prevalence of a disease[2,3,4,5,6]. Large variations reflect uncertainty of proper indications and of differences in resources, financial incentives and care-seeking. Such variations are also powerful for motivating studies on, and action towards quality assurance. Further in obstetrics, area and hospital variations have been documented for operative procedures, such as caesrean sections and instrumental deliveries but not for other treatments or diagnostic procedures[7]. Some interventions are clustered in the same hospitals. This may reflect either a common permissive attitude towards interventions, or it may represent a cascade effect, when one intervention is used, indications for others appear. Diagnostic procedures may cause biological or psychological harm either as such or through false posi-

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tives, and almost all treatments also have side effects. If treatments are used with wide indications, side effects may overcome the beneficial effects which tend to decrease with less serious indications. The value of routine ultrasound screening is not clear[8]. The available literature on the benefits does not support routine use of electronic fetal moitoring[9] or of episiotomy[10,11]. But all these procedures are routinely performed in many institutions in many countries[12]. There is a need for proper randomized clinical trials before new forms of technology are introduced that may become the standard practice despite lacking clearly demonstrated benefits.

In pregnancies detected with very sensitive hormonal assays, almost 60% end in miscarriage before 11 completed weeks of gestation[13]. In around 40% cases causes are known and some may be related to endocrine disorders. Upto 40% of women with recurrent miscarriage (three or more consecutive miscarriages) have been shown to have luteal phase defects which presumably account for their recurrent pregnancy losses[14]. Progesterone has been used prophylactically and therapeutically for over 30 years. However, there is no reliable method for selecting patients who might benefit from hormonal treatment[15,16]. There is hardly any information about the endocrine effects of these hormones when taken during the first trimester. Serum levels of progesterone were not significantly higher in the 17-OHP-C treated group than in the placebo group in the study by Frans et al[17]. The controlled trials also did not demonstrate that progesterone was beneficial in such patients. But the studies often contained both subgroups of women with history of either recurrent or sporadic miscarriage. In view of the high prevalence of luteal phase defects reported in women with recurrent miscarriage, it is possible that a beneficial effect of progesterone in these patients was obscured by large number of patients with sporadic miscarriage in whom progesterone treatment would probably not be beneficial. Since there is a high prevalence of luteal phase defects in patients with recurrent miscarriage, and since progesterone treatment can correct the retardation in endomentrial maturation it is being used[18], in a recent survey, one in six general practitioners in England indicated that they still use a progesterone for this purpose[19]. In addition progesterone and 17-hydroxyprogesterone have not been shown to increase the prevalnce of fetal malformation[16]. Also there is no apparent maternal toxicity from progesterone, as doses of 17 hydroxyprogesterone caproate 20-40 times of those employed in pregnancy have been used in the treatment of endometrial carcinoma without side effects[20]. So it's use in cases where there is strong possibility of beneficial effect may not be refuted. However rationality in it's use is necessary.

Preterm delivery continues to contribute to neonatal mortality and morbidity not associated with congenital anomalies[21]. Although there was much optimism at their introduction, the new tocolytic drugs have not been associated with consistent decrease in the incidence of preterm births. Hospitalization has become the mainstay with the understanding that preterm labour can be diagnosed earlier when the woman is admitted to the hospital. At an earlier stage of labour, the tocolytic drugs are postulated to be more effective in stopping the labour thereby avoiding spontaneous preterm births. On the other hand even long-term hospital admissions for prevention of preterm labour in twin pregnancies have not improved gestational age, outcome[22], struggle what is rational and irrational therapy continues!

The drugs currently used to control severe preclampsia are not always effective in reducing blood pressure and may cause serious side effects in the mother and fetus and so rationality is a must not only in

deciding the necessity of drug but also the preparation. Lower doses of aspirin (60 to 150 mg/day) may have therapeutic value in pregnancy. It has been reported to prevent fetal wastage caused by antiphospholipid antibodies[24]. It may decrease the incidence of preeclampsia[25,26] and fetal growth retardation[27,28], when given prophylactically. But before using aspirin in any therapeutic role in pregnancy one must also consider the maternal, fetal and neonatal effects[29]. Because they reduce the incidence of respiratory distress syndrome and infant mortality in premature infants[13], gluco corticoids are frequently administered in anticipation of premature delivery. There is considerable evidence that fetal exposure to glucocorticoids may affect patency of the ductus arterious[30]. Katz et al[16] report that in human preterm infants antenatal administration of glucocorticoids markedly reduced the incidence of neonatal patent ductus arterious. Valethamate bromide has been used extensively for the acceleration of labour by acceleration of cervical dilation, over more than a decade[31,32]. One study[33] has reported that the difference between the two groups (study and controls) are unlikely to be of clinical significance. However, the study conclusion appears as though it is refuting for refuting sake.

One has to know in any therapy whether it-

1. is unscientific and unethical, or
2. is harmful to unborn baby, or
3. has dangerous side effects.

These facts can be found out by-

1. animal experiments.
2. human trials,
3. accumulation of data from previous studies, and
4. post marketing surveillance.

The abundant literature on variations in caesarean section rates suggests that hospitals with high section rates overutilise it[2,3]. The proper indications for oxytocin and amniotomy are in dispute[34,36]. In England in 1978 the frequency of electronic fetal monitoring of mothers varied from 5% to 95%[37] and rates of caesarean sections in Swedish hospitals in 1983 varied from 8 to 19%[38]. Natzon et al[39] reported consistent increase in caesarean rates over two decades for countries in Europe, North America, and the Pacific. The comparison of prenatal mortality ratios with caesarean section and with operative vaginal rates finds no consistent correlation across countries. Caesarean section rates for fetopelvic disproportion are similar in the Unites States and Sweden, but this complication is diagnosed in almost 5% of US birth and in only 0.4% of births in Sweden.

Knowledge and skills in making decisions must be coupled with responsibile attitudes towards acquiring the best available information, keeping the welfare of patient and the community as paramount.

Gynaecology

The benefits of assisted reproductive technologies to parents and child are a matter of judgement rather than mathematical calculations and depend upon the perceived morbidity associated with infertility[40]. Experience in clinical medicine dictates that individual performance is important, each individual is different, There are simply too many variables involved to hope for a like-with-like study is such situations, it certainly represents a much more realistic way of looking at natural phenomena, sometimes which we as clinicians can immediately relate to on the basis of our own observations[41].

As the pathophysiology of menorrhagia is poorly understood management tends to be unsatisfactory and is in need of improvement. Recent technical developments in hysteroscopic diagnosis and treatment have improved diagnosis. Selective endometrial

destruction has refined treatment. But how effective and how safe are these new techniques? Hysterectomy is advisable if excessive menorrhagia is unresponsive to, or unsuitable for, medical treatment. The hysterectomy rate in 1980 in England was under 20%[25] but rates are likely to be related more to the attitude of women and of doctors towards menstruation than to variations in occurrence of pathology. There is no doubt that hysterectomy is a highly effective way to treat menorrhagia, but cost of this treatment is considerable[42]. An understanding of the underlying causes and the machanisms of abnormal bleeding will allow a more rational approach to treatment of individual women. Diagnostic hysteroscopy with directed biopsy curettage is believed to be the technique of choice for imaging the uterine cavity. This technique usually provides superb view of intrauterine and endocervical pathology[43]. A much less satisfactory alternative is blind uterine curettage. Uncritical adherence to routine use of blind curettage is being questioned and the incidence of false negative results now known to be so high that some say that serious consideration needs to be given to discarding this investigation in favour of the more precise modern methods of imaging and tissue collection[27,28,44]. But there can be many arguments from developing countries against this statement[45].

The beneficial effects of estrogen hormone replacement therapy (HRT) for the prevention of menopausal hot flushes, atrophic changes of urogenital tract, and postmenopausal sleep disturbances have been established[46]. The majority of postmenopausal women in many countries choose not to use ovarian hormone replacement even though the list of indications continues to grow. A major factor contributing to this reluctance is the occurrence of unwanted side effects and fear/scare of malignancy and may be unawareness of availability of this relief measure. However present situation at two ends of the world does indicate necessity of relook in this issue of HRT.

Concluding Comments:

We are involved in a social revolution that is affecting the medical profession as well as other facets of society. Today's physician has inherited the deity status of physicians of the past who relied heavily upon the faith concept for treatment. Review of the condensed medical information supplied by all news media places the public in the position of having some limited knowledge, which traditionally has been known to be a dangerous thing. Therefore, the public demands sometimes unreasonable precision of management and cures that are not possible. Futher lack of understanding of the limitions of scientific advances in medicine, in general, is imposing unrealistic standards of care upon the physician. Any poor result, regardless of the cause, can result in a law suit. Litigation, which is a major problem has accelerated medical costs to an unrealistic level. These costs are not limited to investigative and attorney fees but include unreasonable "defensive medicine" expenses which are believed to be necessary under the present system. It should be recognized that the nature of medical practice is shaped quite as much by patient's expectations and the lay health culture as by physicians and the profession. The judicial, legal, or medical world cannot provide means to adjudicate all the litigations. Specialists cannot look at the insurance industry to help them in solving their practice crisis, for the insurance industry is marching to a different piper. Its primary commitment, like all other industries, is not to be interests of medicine or society but to higher and higher profit for it's stock holders who are believed to be beholders of stony silence sometimes. In addition research in rational therapy should not be restricted to academic Ivory Towers. It is enough to avoid irrationality. Dogma of

rigid end-point of rationality may be better left alone simply because scientific lacunae continue to exist in reproductive medicine to define such a strategy. The problem of irrationality is a challenge to us all. Within this challenge exists an opportunity to identify effective means of promoting rationality. The impact of such effective use may be far greater than the discovery of new wonder therapies.

For managing disorder the treating specialist has to know what has to be done, who has to do it, during what time frame, with what resources and what expectations? Most problems of the third world cannot be solved by technology transfer from the first world. They require solutions developed on the spot. Capacity building in research is essential. In reproductive health care there may be disdain for the concept of health for all, but is probably deeper, arising from conflicts of purpose between pursuing advances in medical science and responding to social needs. A new philosophy for health care and services is needed, a philosophy which emphasises unity across mind, body and spirit and unity across person, community and environment. Compassionate attitude is the key to success in this era of modern science. In this speciality, suitably-evolved health system is needed with strong pillars of medical and ethical values, based on humanity not sacrificing standards anywhere.

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Encouraging Trustworthy Drug Advertising

Dr. Peter Mansfield*

Misleading drug advertising is common and doctors are vulnerable

Most countries lack reliable up-to-date data on the prevalence of misleading drug advertising. In Australia, in 1989 the Australians Society of Clinical and Experimental Pharmacologists reported that 16% to 25% of advertisements in the most popular publication for general practitioners contained 'unjustified' claims[1]. The same year Arthur Yellin of the US FDA reported that "The vast majority of promotional materials submitted for consideration by the US FDA are false and/or misleading."[2] A 1992 study reviewed medical journal advertisemenrts and judged 25% in Brazil, 50% in Finland, 30% in Italy and 38% in Pakistan to be misleading[3].

Although many doctors deny it, advertising works. Controlled trials have shown that advertising techniques are more effective than the methods used in medical education[4]. Avorn et al (1982) found that 63% of a sample of US doctors believed that advertising was of "minimal importance" in influening their prescribing. However, 49% believed that the potency of dextropropoxyphene 32 mg was greater than aspirin 300 mg. The only source of that misunderstanding was advertising[5]. Greenwood (1991) repeated and extended Avorn's methodology. He found that 91% of UK GPs believed that advertisements were of "minimal importance" but 77% had been mislead about dextroproxyphene. He concluded that drug company representatives are the most powerful influence on prescribing[6].

In Australia, the cost of pharmaceutical promotion exceeds the budgets of all the medical schools and post-graduate medical programs combined[7]. The pharmaceutical industry would not spend so much money without having compelling evidence that promotion has a major influence on prescribing. Unfortunately this influence does not always assist quality scientific medical care. Advertisements which gloss over risks not only threaten optimal treatment,but may expose prescribers to the risk of litigation[8].

MaLAM

The Medical Lobby for Appropriate Marketing (MaLAM) is an organisation for health professionals who want pharmaceutical promotion to be trustworthy. MaLAM was designed by the author who was distressed to see scientific medical care under attack from misleading drug promotion whilst on a medical student's elective in Bangladesh in 1981. "Appropriate Marketing" refers to health-related marketing with provision of appropriate information to assist health professionals to provide appropriate compassionate scientific medical care. "Medical Lobby" refers to an organisation which conveys the concerns of health professionals in ways that encourage appropriate marketing.

MaLAM is a non-profit organisation providing:

a) dialogue between health professionals and pharmaceutical companies.
b) support for quality scientific medical care.
c) encouragement for reliable pharmaceutical promotion.

MaLAM's method

Every month a MaLAM letter addressed to a pharmaceutical manufacturer is prepared by Secretariat with members in Australia, Canada and France. Topics are cho-

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sen from the most serious of many complaints received from health professionals around the World. However, MaLAM letters are designed as request for information rather than complaints.Most of the letters quote a questionable promotional claim, provide a summary of the scientific literature for comparison and ask the manufacturer for evidence to support the claim. Copies of a MaLAM letter and MaLAM News (in English or French) are sent to over a thousand subscribers, most health professionals in over thirty countries. Subscribers support the letter be requesting a personal copy of the answer from the manufacturer. No pharmaceutical company can ignore request for information from large numbers of health professionals. The ensuing dialogue is reported in MaLAM News and other medical journals. These reports assist health professionals to determine for themselves whether the manufacturwer's claims are reliable and what place the drug under scrutiny should have in their clinical practice.

Successes

Dr. J.F. Dunne, Director' Division of Drug Management and Policies, WHO, has written that "the objectives of MaLAM are widely acknowledged and appended." The Australian clinical pharmacologist Prof. A.J. Smith has declared that MaLAM "has made a substantial impact on grossly inappropriate marketing in the developing world."

MaLAM letters are usually followed by improvements in marketing, occasionally as dramatic withdrawal or reformulation of the drug. Reports of MaLAM's impact have been published in the Lancet on five occasions and elsewhere[10-15].

Improvements gained following MaLAM latters include withdrawal of:

- an arsenic/strychnine/glucose/alcohol combination for psychological stress.
- nikethamide for neonatal respiratory distress.
- a phenobarbitone/ephedrine/theophylline combination for asthma.
- uridine triphosphate for children with delayed development.
- a gonadal hormones/vitamins combination as a tonic for the elderly.
- a furzolidone/metronizaole/kaolin/pectin combination for diarrhoea,
- aspirin for febrile children.
- a neomycin/kaolin/pectin combination for diarrhoea.
- a chloramphernicol/streptomycin combination for diarrhoea.
- an ammonium chloride/guaiphenesin/trimethoprim/sulphamethoxazole combination for bronchitis.

MaLAM is not adversarial

It is understandable that many industry executives perceive MaLAM in adversarial terms but that is not justified. As the author explained in an open letter to industry in 1989 : "MaLAM is not an anti-industry organisation. By contrast, we are keen to counter the widespread belief that the drug industry puts profits before patient care, by providing that you are capable of reform. Our aims are positive. MaLAM's aim is to encourage pharmaceutical companies to provide reliable information to assist appropriate therapy. Open, honest communication between health professionals and yourselves is essential for the advancement of scientific medicine. Scientific medicine aids not only us and our patients but is also the best path to increasing your future profitability. We believe that many of you in the industry are working for reform and we hope that our encouragement will help you"[18].

MaLAM Australia

Until recently, MaLAM has focused almost exclusively on advertising published in "developing" countries. However, MaLAM has recently accepted a two year grant from the Australian Government Pharmaceutical Benefits Scheme Education Programme to

establish MaLAM Australia. This subsidiary is focusing on misleading promotion published in Australia. MaLAM Australia has already won widespread support from Australian health professionals. The new Advisory and Editorial Board include representatives of the Australian Medical Association, Australian Nurses Federation, Pharamaceutical Society of Australia, Society of Hospital Pharmacists of Australia, Royal Australian Colleges for General Practice, Obstetrics and Gynecology, Physicians and Psychiatrists. Reports of MaLAM Australia's activities have appeared in a wide range of publications including Australian Doctors Weekly, Australian Prescriber, Lancet and Scrip[17-20]. In the long-term MaLAM will remain funded primarily from subscriptions to ensure that it is, and is seen to be, a voice for health professionals.

Future plans

Continued expansion of MaLAM's international operations is a high priority. For example MaLAM is currently seeking funding for transition of its international editions into a Spanish MaLAM. MaLAM hopes to establish national organisations similar to MaLAM Australia in mny other countries. We are looking for an appropriate organisation to act as our agent in India.

MaLAM is considering the establishment of a self-regulation support service in Australia. This service would seek expressions of concern from health professionals regarding therapeutic claims of all types. It would then provide properly documented complaints to the appropriate self-regulatory bodies. When necessary MaLAM would also assist the self-regulatory bodies with the dissemination of corrective information. As Harvey concluded in 1988 "Co-regulation rather than self-regulation might achieve more acceptable standards of pharmaceutical promotion"[21]. Neither government nor industry can achieve the best results alone. Health professionals must work together to make it clear that we want pharmaceutical promotion to be trustworthy.

Enquires are welcome. Please contact:

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Rational Fixed — Dose Drug Combinations

Dr. Anant R. Phadke*

Majority of the drugs available in India are in the form of combination of two or more drugs. Available studies (1 to 5) indicate that most of them are irrational. They either contain addition of one or more unnecessary ingredients to the main drug or are presented in wrong dosage. Moreover, many of the drug-combinations are "me-too" drugs, i.e. drugs which contain a very slight, inconsequential change in one of the ingredients or a minor change in the dose of the same ingredient as compared to the similar conbination maketed by some other company. These "me-too" irrational drugs, marketed under different brand-names and/or in different packages are a menace. This is because they are unnecessarily costly, are irrational in the first-place, confuse the doctor and the patient by their similar sounding and some times very exotic, queer brand names; and it's almost impossible for the drug-control authorities to monitor either the quality of the hundreds of formulations of the same category of drug or their prices. The drug action groups in India have, therefore, been demanding a ban for all the irrational drug combinations. Under popular pressure, the Government of India set up a subcommittee of the statutory drugs consultative committee for weeding out irrational and hazardous drugs marketed in India. This subcommittee has been examining one category of drug after another to determine which drug-combinations in that category are irrational. This committee does not meet often and basically, the procedure of case-by-case examination will take a very longtime, because there are scores of categories of fixed-dose combinations (FDC's). The progress of this committee has been very tardy, and it will take years to review all categories of drug combinations maketed in India. Secondly, for majority of such drug-combinations, there are no scientific studies available to assess their efficacy and safety. This is because, drug companies have been marketing all kinds of queer, irrational drug-combinations and researchers have naturally not studied them; there is no point in studying the comparative efficacy and safety of absurd combinations. Yet, the Drugs Controller, India, has allowed the study of comparative efficacy and safety of the absurd combination of analgin with oxyphenbutazone, when both the drugs themselves are under a cloud. Apart from the absurd nature of this combination under study, one or two studies cannot be relied upon to take policy decision about banning such drug-combinations.

The way out for this situation is to rely on the recommendations of standard medical textbooks and renowned national formularies and ban all fixed-dose drug combinations, not recommended by these authorities. The recommendations of such world-renowned authorities are based on careful evaluation of all the studies on the drugs concerned. Unless there are some special reasons to differ from the recommendations of these standard authorities, we should follow these recommendations and ban all other FDC's. Given below, is the list of rational FDC's, based on the recommendations in standard medical textbooks and renowned national formularies (6 to 10). This list was prepared as part of the larger study, that we conducted - "A Study of Supply and Use of Pharmaceuticals in Satara District". There could be a few changes and additions to this list. But all other FDC's marketed in India are irra-

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tional and should be banned. The list given below, only specifies various categories of drugs. The number of drug formulations would be larger, because many drugs would be available in two or three dosage forms, (say penicillin tablet, dry syrup, injection) and sometimes two drugs belonging to the same category may be used (for example inhibitor of beta-lactamase). A comprehensive list of all rational FDC formulations is yet to be prepared. The list below, gives only the categories of drugs, grouped according to the rationale of their combination. It can be a starting point for preparing a comprehensive, detailed list. The drugs marked below with an asterisk, are included in the WHO Essential Drug List.

Rational Fixed-Dose Drug Combinations

a) Synergism:

*i) Oestrogen - progesterone combination in oral contraceptive pill.

*ii) Glucose plus sodium chloride in ORS powder.

iii) Ganglion-blocking antihypertensive plus thiazide diuretic.

*iv) Trimethoprim plus sulfamethoxazole.

*v) Sulfadoxine (or equivalent sulfonamide) plus pyrimethamine for resistant P. falciparum malaria.

vi) Beta-lactamase susceptible beta-lactum antibiotic plus inhibitor of beta-lactamase (clauvulanate, sulbactam).

vii) Fluocytosine plus amphotericin B in cryptococcal meningitis.

*viii) Benzoic acid plus salicylic acid as antifungal ointment.

*ix) Levodopa plus carbidopa for Parkinsonism.

x) Aspirin plus codeine for analgesia.

xi) Vitamin D with calcium for better absorption of calcium.

b) When two or more drugs are often needed together in invariable proportion:

*i) Iron plus folic acid.

ii) B' complex.

iii) Polyvitamin.

iv) Vitamin A and Vitamin D (the dietary sources of these nutrients are the same, hence deficiency is often of a combined nature).

v) Isoniazid plus rifampicin, isoniazid plus rifampicin plus pyrazinamide (to reduce emergence of drug resistance).

*vi) Isoniazid plus thiacetazone (for the same reason as in v).

*vii) Inj. dextrose-saline and inj. Ringer's-lactate.

viii) I.V. Darrow's solution or Hartman's solution.

ix) Intraperitoneal dialysis solution.

x) I.V. solution for total parenteral nutrition (TPN).

c) For corrective action :

i) Isoniazid plus vitamin B-6 (B-6 prevents peripheral neuritis caused by. prolonged use of isoniazid).

ii) Ephedrine plus phenobarbitone

(phenobarbitone counters the nervous system stimulation of ephedrine).

*iii) Magnesium hydroxide plus aluminium hydroxide (the latter tends to cause constipation, the former is a laxative).

d) To increase the range or duration of action

*i) Neomycin with bacitracin local ointment.

ii) Insulin mixtures (to have a 24 hour, stable action).

iii) Inj. lignocaine with adrenaline (adrenaline causes vasoconstriction and prolongs action of lignocaine).

iv) Inj. benzylpenicillin with inj. procaine penicillin (to get quick onset with 24 hour action).

*v) Inj. DPT, inj. DT vaccine.

*vi) Inj. polyvalent anti-snake-venom serum.

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European Drugs in Developing Countries : Problems Remain Unsolved

Bas van der Heide*

The nature and extent of the problems involved in the export of drugs to developing countries has been the subject of several studies. In May 1994, a group of Dutch researchers published their study "Dutch Drugs in Developing Countries" (1), one year after the publication of a study for the American Congress into the labelling practices of American companies. This study included a range of policy recommendations, but was released at a time that President Clinton and the Congress were over whelmed by the work on their national health plans. Its fate so far has been the famous dusty drawer. Does the Dutch study give any inspirations for opening the political debate in Europe? In this article it is argued that many problems remain unsolved.

Dutch drugs in developing countries

The study "Dutch Drugs in Developing Countries" was done on the request of the Dutch Ministry of Health, prompted by discussions in the Dutch Parliament. Its findings all but equal the results of similar policy studies. Of the 161 drugs that could be evaluated, 42% were considered problem drugs. Product information was lacking in a third of the drugs, indicative of the difficulty to obtain adequate drug information in developing countries.

The first aim of the study was to find out which problem drugs were supplied by Dutch companies to developing countries and on what scale. The second aim was to assess the quality of the product information of the drugs exported by Dutch companies. In order to do so the labels were compared with the registration requirements in the Netherlands. Local researchers obtained Dutch drugs in pharmacies in Ecuador, Surinam, Nigeria, Thailand, India, the Philippines, and Sudan.

Dutch drugs were defined as drugs manufactured and/or exported by Netherlands- based companies, but also those drugs that were produced by subsidiaries of a company based in the Netherlands. The evaluation was based on the principle that drugs for export should be safe and effective and that product information should be provided with them that does not differ in pharmacologically relevant respects from the Dutch product information.

Bad product information

Relatively few cases involved problems concerning the substance, the so-called problem drugs (5%). Of the drugs evaluated the percentage of essential drugs varied between 0% in Nigeria to 40% in Sudan. A great number of problems was related to the product information, showing inconsistencies in listing side effects (15%), contra-indications (12%) and inconsistent warnings (9%). Frequently there was no warning against the hazards of using the drug during pregnancy. Most problem drugs were encountered in areas where the involvement of Dutch manufacturers was lowest, e.g. production by local subsidiaries.

Similar findings

The findings of the Dutch study all but equal the percentages found in the study by the Office of Technology Assessment (OTA) for the US Congress about the labeling by

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Two Indian drugs which may cause serious public health consequences

1. ***Docabolin (R) Injection, produced by Infar, India (under licence by Organon). Generic name: nandrolone phenpropionate + desoxycortone phenpropionate. This product is not marketed in the Netherlands. It is evaluated as follows: "Combining two totally different drugs (as anabolic steroid and a corticosteroid) in one injection is undersirable. If the drug is taken for its anabolic qualities there is an undersirable suppression of the adrenal gland and consequently of resistance. If the drug is used as a corticosteroid all sorts of anabolic symptoms may occur."(2)***

2. ***Mixogen (R) tabl, produced by Infar, India (under licence by Organon). Generic name: ethinyl estradiol + methyltestosterone. This product is not marketed in the Netherlands.It is evaluated as follows: "There are no indications for a combination of estrogen and a testosterone derivative. Taking the drug may cause serious adverse effects to the genitals as well as psychological disorders. Availability in tablet form can lead to misuse." (3)***

American companies of their drugs exported to developing coountries. They found that of the 241 drugs sampled, two-thirds failed to provide the labeling informations a physician needs to use the drug safely and effectively (4). Recent studies into the French drug exportations found similar problems with double standards in labeling and advertising. Often the indications are wider, whereas the section on warnings and contra-indications is smaller. Without a basic structure there is nobody to interpret information about drugs, now would there be any chance of effective control on restrictions on the drug market. Pointing at the real gaps in product information, the researchers argue to focus on improving the exchange in information about drugs. They also argue not to allow double standards for information with exported pharmaceuticals (5).

This touches upon the second basic question regarding drug exports. Should the export of certain products be banned (with room for exceptions), or should exporting countries allow other authorities to make their own decisions? Phrased in this way, it is clear that many authorities would prefer the second option, because it does not interfere with their sovereignty and would allow different risk-benefit considerations. These are acceptable as they are result of an informed choice.

For example: a product may be safer, but be ten times more expensive. Countries with a few dollars to spend have no choice but accept the cheaper product. In order to make an informed decision one needs a total picture about a drug, in an understandable format and at the right time.

Which possibitities do importing countries have to make their own informed choices? The mere exchange of information on whether the producer follows Good Manufacturing Practices (GMP) and the provision of basic information about the drug, as provided by the "WHO-Certification Scheme for the Quality of pharmaceutical products moving in International Commerce" is not enough in itself. The information does not cover safety and efficacy data. In addition the Certificates issued by European authorities are not always WHO type documents, leading to a very confusing situation. The information in the documents is based on regulatory situations that are very

difficult to understand. Which drug regulator in Africa knows that of the 50,000 products on the German market only a small percentage has been checked for safety and efficacy? Which regulator did understand that under the old French law the Free Sales Certificate meant that the product was not actually sold on the French market, but that export was allowed? A "Rough Guide to European Documents" would probably help many confused drug regulators in the world.

The Dutch study argues for stricter measures in the exporting countries. One of the areas is the further harmonization of EU member states' export legislation. Most European countries do not require drugs intended exclusively for export to be submitted to a registration procedure. Under the law in the European Community (adopted in 1989) companies do need a licence for being a manufacturer of drugs, also if they produce for export only. Specific drugs however, do not need a licence if they are intended for export outside the Community. In addition countries have to comply with the WHO Certification scheme and include a summary of product characteristics with this document. In 1989 the European Parliament failed to further tighten the European Community law to banning the export of drugs that had been banned, writhdrawn or severely restricted, or that had never been licenced in the Community (6).

France and Germany take the lead

Since the adoption of the law for the European Community some countries have adopted export provisions that add to the very basic European requirement. Newly-introduced provisions in France (1994) and Spain (1994), for example, prohibit the export of drugs whose licence has been suspended or withdrawn for public health reasons. Under the German Drug Law (1989) it is prohibited to export "doubtful" drugs. However, drugs products may be exported whenever the competent authority of the importing country has authorized importation, even if a marketing authorization was refused in the exporting country. In this case, the importing country must be aware of the reasons for the refusal of the marketing authorization.

France has banned the export of drugs which have been withdrawn from the French market for safety reasons, and of drugs whose registration has temporarily suspended for safety reasons. The Minister of Health may, for public health reasons, ban the export of any drug. The exportation of drugs without a French licence needs to be accompanied with an export certificate. In order to get this document from the French regulatory authorities, the company has to explain in an export declaration why the product is not authorized for sale on the French market.

Chances for European harmonization

The Dutch researchers specifically refer to the German and the French law as a basis for further European harmonization. Unfortunately there is a big gap between law on paper and enforcement in practice. The German drug law had to be implemented by the drug control authorities on regional level. To date however very few steps seem to have been taken to implement this law. The French law is too fresh to evaluate, but could become highly relevant in improving the flow of information about drugs exported to francophone Africa.

What would additional export provisions add to the alreay existing measures? Would it improve the flow of information to developing countries? The key element of the French and German law is a ban on the export of banned, unapproved, and withdrawn drugs, as well as on drugs whose use is restricted in the home country. Exceptions to this default situation can and should

be made, but the manufacturer has to apply for a licence. With this exception-to-the rule principle, the export of unlicensed drugs remains possible in cases where this is proved to meet the needs of the developing countries. Such provisions can also function as a notification procedure parallel to other measures and as such be an extra safeguard for more transparency about the drugs and the drug information coming from Europe.

Complication

From the above it follows that the case for stricter European export legislation is clear. But translating it in terms of procedures and practices has proven to be very difficult. The discussion has been further complicated by the fact that most of the export provisions are too fresh to be fully evaluated on their effects. One could look at the American export policy, which has been revised in 1986. Under this law, exportation of non-registered products is permitted only to countries with comparable systems of regulatory control (22 countries), and for products indicated for the treatment and prevention of tropical diseases. Apparently this policy has not hampered the US industry, nor that it damaged the clinical development of relevant drugs, like ivermectin for onchocerciasis and eflornithine as a treatment for African trypanosomiasis.

Another complication for the discussion in Europe has been the absence of one strong and transparent European drug regulatory authority. So far licensing and drug export policies in the European countries continue to be so different that it would be difficult to find a standard definition for the key categories of products whose export should become restricted.

Studies like "Dutch Drugs in Developing Countries" should serve as a reminder of the importance of the issue. The problems with drug labelling merit a closer look in international form, like the European Union, ICDRA and WHA. Policy recommendation need to be looked at by all parties concerned, allowing developing countries to be become fully involved in this discussion.

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The Role of Pharmacists in Primary Health Care

Beverly Snell*

The contribution of pharmacists to the health care system is based on many years of training followed by continuous practical experience. Pharmacists are community and hospital pharmacists, specialists in scientific activities, researchers and educators and managers and administrators. Increasingly, pharmacists are Primary Health Care (PHC) team members. This paper focuses on the expanded role of pharmacists as members of the PHC team and their special role in the promotion of rational use of drugs.

Primary Health Care (PHC) is essential health care based on scientifically sound and socially acceptable methods and technology, made universally accessible to individuals, families and communities by their full participation. Provision of essential drugs is a crucial component of primary health care even though it usually comes last on the list of PHC components as can be seen below.

PHC includes education concerning disease theory and prevailing problems, and focuses on finding methods of prevention, rather than emphasising cure. It includes:

- specialised maternal and child health care (MCH) with immunisation against major diseases and education towards child spacing;
- nutrition education;
- education for prevention and control of locally endemic diseases,and for appropriate treatment of common problems and injuries;
- promotion of adequate production of appropriate food;
- integration with other social and community activities to ensure an adequate supply of safe water and basic sanitation;
- provision of drugs essential for the REAL need of most of the people.

Pharmacists in PHC

Pharmacists are ideally suited for the role of coordinating every aspect of the drug program in the PHC system. The two main aims of an Essential Drugs Program are:

- regular Supply of appropriate drugs;
- correct use of the drugs.

Associated with these two main aims are many integrated activities which cannot be separated from an Essential Drugs Program. These include:

- at the national level, development of a Standard Drug List, based on treatment guidelines for the most common diseases, in collaboration with other medical personnel;
- procurement of all these drugs in adequate amounts;
- stock control and record keeping;
- education of the staff;

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- education of other health professionals;
- education of community leaders;
- education of the public;
- evaluation of information gathered;
- adjustment of the drug lost if necessary, in consultation with other team members;
- orientation of all the above concerning perceptions of disease and the role of essential medicines.

Integration with PHC Team Activities

The activities which are included in a PHC program involve a range of Health Professionals, Technicians and Community Health Workers, who find their original formal training only covers a small part of what become expected of them. Nurse Administrators, Midwives, Pharmacists, Sanitarians, Nutritionists, Statisticians, EPI staff are all part of a PHC coordinating team, often led by he Medical Coordinator, usually a Medical Doctor. Members of the team share their information and work out their programs together. The integration of disciplines can be seen in the following examples :

- Control of water borne disease needs health education, good water supply and sometimes medicines in the meantime, for curative purposes.
- Pregnant women need good antenatal care which involves nutrition education and may need attention to harmful cultural practices. They may need therapeutic medicine for anaemia or management of blood pressure in the later stages. Awareness is needed to the dangers of certain drugs during pregnancy and lactations.

The Special Role of the Pharmacists

In PHC, pharmacists are much more than efficient storekeepers and dispensers. With the support of Drug Information Pharmacists, pharmacists provide information for the development and review of the Standard Drug List and Treatment Guidelines. In addition, the 'chief pharmacists' in the Regional PHC team is the 'head of department'of the essential drugs component of the PHC program. This is a person with a good concept of the whole program, its aims and ideals, who also participates in training and supervision of all who involved with the use of drugs. This person is also capable of coordinating store maintenance, ordering, distribution and record keeping, and of training others to perform these activities so that he does not become buried in the 'housekeeping' activities at the expense of the training and supervision necessary to ensure the Rational Use of Drugs.

The Need for a Standard Drug List

Although the emphasis of PHC is on prevention rather than cure, medicines and curative services are needed. It is important to have the most appropriate medicines available always. The best way to make sure the most appropriate medicines are available is to make a Standard Drug List. Survey of the disease patterns will allow the policy concerning essential medicines to be aimed at the real needs of most of the people.

In the PHC as mentioned above, there are different levels of care in the system, so there needs to be careful selection of the different medicines which are most suitable and most effective for the different levels. There has to be a choice by the policy makers so that suitable medicines will be available always, and the money available will be used in the best way.

Review of the Drug List

The Drug List is a 'living tool' for improving the health of the people. It needs regular assessment and adjustment, if necessary. Regular review workshops present

opportunities for people to recommend changes in listed drugs or their use. Recommendations should be notified well in advance so that all necessary references can be acquired and informed decisions can be made during the workshops.

Even when drugs are carefully selected to be appropriate for the needs, it is still possible that inappropriate treatment can occur and drug can be wasted if the prescribers have not been sufficiently familarised. The best way of assuring appropriate prescribing of essential drugs is with the use of Standard Treatment Guidelines.

Standard Treatment Guidelines

Standard Treatment Guidelines are the key to an appropriate uniform approach to the management of common disease. If these guidelines are known throughout the country appropriate treatment with medicines will always be available whether it is from a doctor, a health worker, a nurse or a commercial pharmacist. Different categories of drugs can be identified from the list for use by different levels of health workers. For each level the prescribing limits will be specified:

(a) Drugs which can be used by primary health workers like VHWs and TBAs;

(b) Drugs which can be used by middle level health professionals;

(c) Drugs which can only be used by doctors at the hospital level.

Commercial pharmacists might be included in b or c.

When different categories of health workers have already been developed, a survey of their skill will help define their responsibilities. Based on the survey findings future training can be planned, and prescribing guidelines can be worked out.

Community Activities

Health workers chosen from their communities can be trained to undertake most of the PHC activities in their communities. In most PHC programs their work includes prescribing and dispensing medicines. They will be trained, upgraded and supervised on the job by professional health workers, including pharmacists, who need to be very familiar with all aspects of PHC since they are the on-the-job teachers. The teachers will also need to be available for helping with problem-solving at the community level, in consultation with community members.

Training Workshops

During periodic workshops knowledge about the use of medicines (when medicines are needed) is upgraded. This increases the confidence of the personnel to identify problems and to recommend changes in prescribing. Such workshops also help to increases confidence to identify and teach about situations where medicines are not needed.

★ It is much harder to avoid prescribing than to always prescribe.

★ The communities need to be convinced.

It is also important for pharmacy teachers to be aware of common medicines that are available in local commercial pharmacies and from drug vendors, and to know about their possible dangers and unsuitability. It helps if they can explain to people who do not understand the difference between appropriate and inappropriate treatment with medicines. During workshops, discussion of local problems and how to address them can be very helpful. Sometimes the chief regional pharmacist will need to accompany the on-the-job teachers so they can share their knowledge about the appropriate use of medicines with the communities.

Supervision and Evaluation

The importance of supervision and evaluation cannot be over-emphasised. Active supervision of perescribing practice, for example to observe clinic records will identify discrepancies in prescribing and identify targets for education. In addition, clinical supervision of health workers, particularly at the peripheral level is a means of on-the-job training, sharing of new information, and helping with problem-solving.

Supply to the Program Related to Supervision

In PHC, pharmacists play an active educational role. This means that requests for medicines are evaluated by the pharmacy staff and they are not automatically filled. Regional and district staff can discuss the requests and the health statistics recorded in the patient register, together, to understand the implications of the information provided, during visits to the health facilities. Presentations of order forms and interviews in the regional capital along, cannot possibly give a picture of what is really happening in the program. Analysis of patient records together with drug requests can raise questions, the answers to which can provide an important picture of what is going on.

The following examples show how discussion of simple drug order forms, during a visit by pharmacists to a health clinic, can link into the whole range of PHC activities. The supply of medicines is not an isolated component of the program, but an integral part of the whole development of improved health of the community. Supervision on-the-job, in the community, by Regional staff, should be an important priority. This supervision ensures that there is correct understanding of what has been taught, and it will help orientate the community towards the correct use of medicines.

Is treatment in accordance with the National Standard Treatment Guidelines ? If not why not? May be the deviation can be justified. May be the prescriber does not understand the guidelines.

Antibiotics are used very quickly. Why? If there is an increase in the use of antibiotics for diarrhoea, is it in response to patients saying they have blood in their stools ? Are the patients misleading the prescriber in order to have antibiotics prescribed ? Is there really a problem ? Why ? May be there has been recent rain and people are getting their water from polluted puddles rather than the clean source which is further away. This identifies a need for health education in the community. The Regional Medical Coordinator can be called in to help if necessary. May be the normal water supply has become polluted and it is necessary for the sanitarian and water engineers to be asked for advice about solving the problem.

Many iron tablets have accumulated, or none have been ordered for months. Are health workers looking for anaemia in the presence of malaria ? Are they caring for pregnant women properly ? Would it help to involve opinion leaders from among the women in the community?

There is an accumulation of drugs which are badly stored and hard to see, resulting in even more being ordered.

Is there increased use of choloroquine? Is the diagnosis correct? Is some action necessary like a malaria prophylaxis campaign? Reports of these sorts of trends should be shared with the whole term so that necessary action can be taken.

There is an increase in malaria. Is this increase in malaria accompanied by vigilance for anaemia and increased use of iron tablets? If not, why not? May be some community perceptions need to be addressed.

No ORS has been ordered although diarrhoea is commonly reported in the patient register. Is there some difficulty with convicing either the health workers or the community about the role of rehydration ?

Is the patient register accurately filled in, including all details of treatment ? Comments like 'plenty of fluids recommended' need to be recorded also as part of appropriate treatment.

The information gained makes an important contribution to the whole PHC program. Figure 1 shows how an iterative cycle of management is applied in the Essential Drugs Program of a PHC program.

Supervision on-the-job and Evaluation in the Community

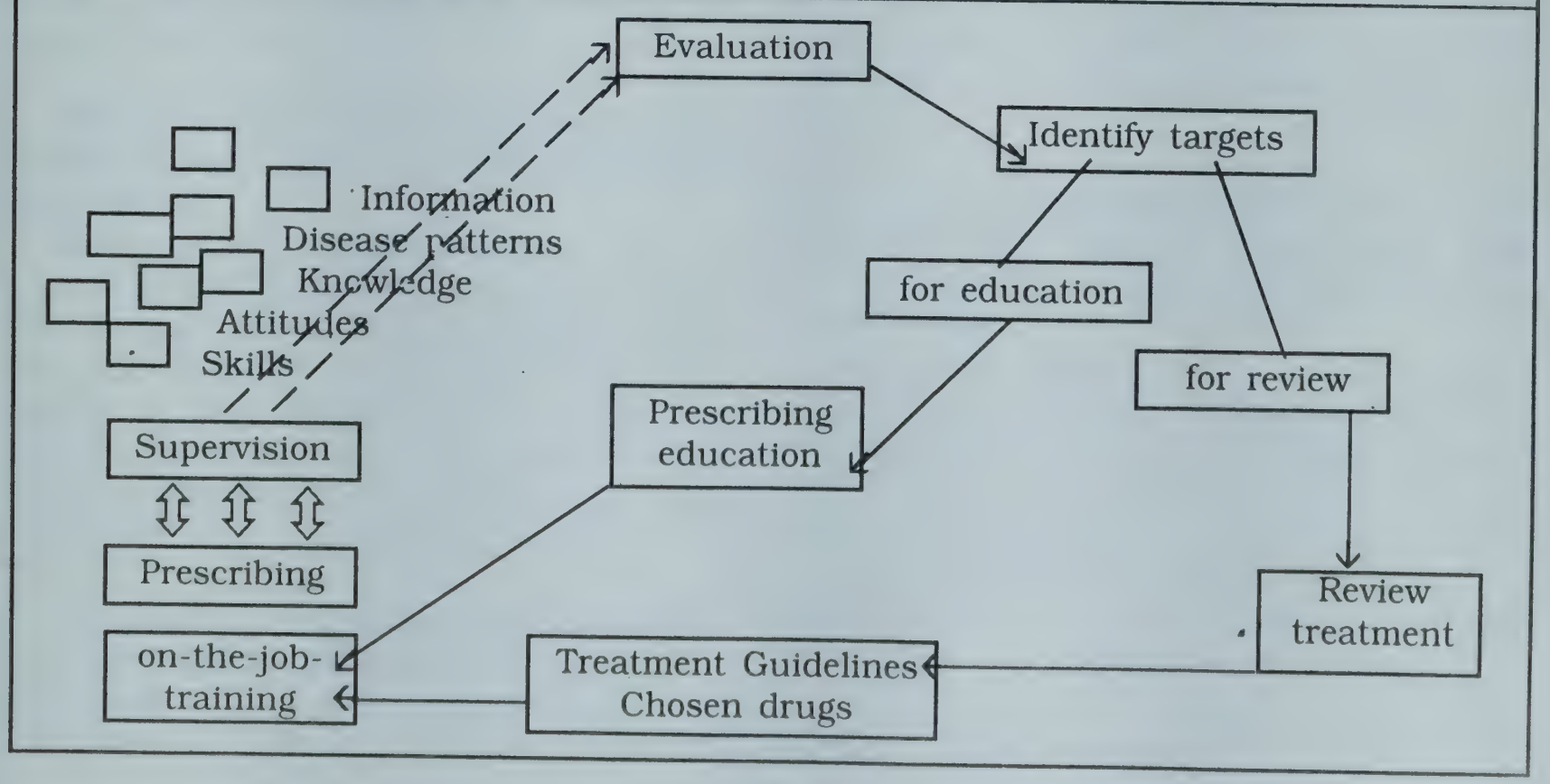
Health workers and other staff are often under pressure to give medicines on request. The PHC staff who are prescribing in the health services need support for their efforts to educate the community towards what may be considered a new concept. From the more experienced team members, and from the regional team members, particularly the Regional Medical Coordinator, the staff can learn, and later develop the capacity to see, evaluate, and respond appropriately on the spot.

It is absoutely vital that the staff of the drug program do not neglect their responsibilities in the field because of the pressure to keep things in order at the central level. Preparation of a work plan which includes time for distribution and recording but reserves time for team meetings and supervisory visits and teaching sessions can help. The supervisory visits and the relationship with the functioning PHC program are the most interesting of the pharmacist's responsibilities. Rotation of tasks helps to stimulate the staff and helps prevent boredom with the mundane but necessary tasks. It is at the periphery of the program the Primary Health Care lives, and it must be kept alive with a living connection to the centre.

Use of Curative Service as the Gateway to Promoting PHC

The occasions when medicines are prescribed can be used as oportunities to in-

Figure 1. Iterative cycle of management as applied to an Essential Drugs Program



troduce the patients to the idea of preventive measures and health education. Good nutrition can be promoted rather than the need for nutritional supplements, management of diarrhoea with ORS can be explained and measures to prevent worm infestation in the future can be explained when worm tablets are prescribed.

Obstacles

The implementation of an Essential Drugs Program and PHC will always meet obstacles in the community where people are used to have access to a wide range of medicinal substances on request. In addition, some prescribers resent 'restriction on their freedom'. They will soon understand an Essential Drugs Program will help the effectiveness of their services and ultimately improve the care of their patients.

About the author

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How to Improve Your Prescribing : Some Useful Tips

Dr. Santanu K. Tripathi*

1. Prescribe drugs only if your patient needs them.

Writing a prescription does not necessarily mean it must contain drug(s). Your patient may not need any drug. Non-drug treatment and simple advice may suffice in many conditions.

2. Take your time in prescribing the right choice medicine for your patient. If needed, feel free to consult a guide-book or formulary ready at your disposal.

While prescribing any drug, always take into consideration factors such as age, sex, weight of the patient, presence of renal or hepatic dysfunction, effect of other diseases present, effect of other drugs taken by the patient simultaneously, pregnancy, breast-feeding etc.

3. Before prescribing, elicit complete medication history from your patient.

Enquire from your patient about drug allergies, Ask if s(he) is taking any drug(s) at present and if so, what drug(s), check for possible drug interactions.

4. Do not yield to pressure and persuation by the patient while you are writing the prescription.

You know more than the patient what is best for him(er). Explain to your patient: injections are not always the best form of treatment, newer drugs are not necessarily better agents, constlier medicines are not always superior, tonics are unnecessary, vitamins have only a very limited role and may be need only in rare cases of true deficiency states.

5. Do not let yourself swayed away by the promotional gimicks and claims by the drug companies.

Informations on drugs and the therapeutics provided by the drug companies are often misleading, exaggerated and biased. Always try to corroborate them in independent and reliable information sources.

6. Avoid the temptation of prescribing the 'latest drug'.

It is wise to be behind the fashion in matters of drug treatment. 'Wait and Watch' is the best policy in this regard.

7. Avoid prescribing multi-ingredient fixed dose combination (FDC) preparations as far as possible.

Barring a few FDC preparations that are scientific and have significant therapeutic advantage, all others do not have any rational basis.

8. Do not prescribe injections unless they are really needed.

Unnecessary injections not only add to the cost of the prescription but they also carry extra risk of transmitting viral hepatitis or AIDS.

8. Avoid prescribing 'placebos' as far as possible. Good rapport, reassurance and counselling may serve the purpose most of the time.

If writing a placebo is 'absolutely necessary', ensure that you are doing this not as a means of fobbing off your patient but of bringing relief without harming him(er). Choose a safer and cheaper drug as placebo eg., vitamin C or vitamin B complex tablets. Never prescribe injections as as placebos. Never prescribe tranquilizers eg., diazepam, as placebos.

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10. Avoid polypharmacy.

If you prescribe drugs, write only as many as your patient needs. The more drugs you prescribe, the more risk you invite : the risk of poor compliance, the risk of wider spectrum of adverse reactions, the risk of adverse drug interactions and so on and so forth.

11. Develop the habit of prescribing in generics.

Generic prescribing avoids confusion, minimizes cost of treatment, is more scientific and ethical.

12. Consider the total cost of your prescription and ensure that the patient can afford it.

If the patient cannot afford the cost of the prescription, the compliance would surely be compromised and this may have dire consequances.

13. Give clear and legibly- written instructions using simple language.

Always mention the full dose regimen i.e., dose size, route of administration, dose frequency, duration of treatment etc. Avoid using unofficial abbreviations and phrases like "to be used as advised". Simple illustrations (pictorial) may improve compliance greatly.

14. Honour your patients' right to be informed.

Spend a little more time in explaining to your patients how the prescribed medicines are to be taken, what are possible side effects, if any special precaution is to be taken, what to do if a dose is missed or forgotten, how to store the medicine, what to do in case of accidental overdosage etc.

15. Do not forget to mention the diagnosis.

At least a provisional diagnosis or a few differential diagnoses should be mentioned.

16. Always write the prescription in all completeness. Remember that it is also a legal document.

Make sure that the prescription carries your identity as the prescriber (your name, academic qualifications, address, telephone number, if any), the patients' identity (name, age, sex, address) and the date of prescribing. Also keep note of all relevant informations (including the negative findings) and instructions to the patient in regard to safe use of medicines prescribed.